THE COMMUNITY PHARMACISTS' ROLE ENHANCING MEDICINES MANAGEMENT FOR TYPE II DIABETES IN TRIPOLI, LIBYA

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THE COMMUNITY PHARMACISTS' ROLE ENHANCING MEDICINES MANAGEMENT FOR TYPE II DIABETES IN TRIPOLI, LIBYA

A RANDOMISED CONTROLLED TRIAL IN COMMUNITY PHARMACY TO INVESTIGATE KNOWLEDGE AND PRACTICE IN RELATION TO TYPE II DIABETES AND GLYCAEMIC CONTROL

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Abstract

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The Community Pharmacists' Role Enhancing Medicines Management for Type II Diabetes in Tripoli, Libya

A Randomised Controlled Trial in Community Pharmacy to Investigate Knowledge and Practice in Relation To Type II Diabetes and Glycaemic Control

Key words: Type II diabetes, diabetes knowledge, self-management, diabetes attitudes, fasting plasma glucose, HbA1c, pharmaceutical services, pharmaceutical care, medicine management

Aim/Objectives: There were two aims; improving type II diabetes glycaemic control; and enhancing the role of community pharmacists by engaging them in type II diabetes medicine management.

Methods: This quantitative study collected data from both community pharmacists and patients. In a premises survey, 426 self-administered questionnaires were distributed to community pharmacies. In a knowledge survey, 125 questionnaires were distributed to community pharmacists. In a clinical trial, 40 community pharmacies were randomly assigned to be control (18) and intervention (22) premises. Each pharmacy recruited 4 or 5 patients with type II diabetes. 225 patients were recruited and assigned to receive usual pharmacist care (n=100) or a pre-defined pharmacist intervention (n=125).

Results: Community pharmacists had good knowledge of diabetes with average scores 21/29 (±3.18). The differences between control and intervention groups in patients' HbA1c and FPG changes were not significant. In the intervention group patients' diabetes knowledge was significantly improved (p=0.031). In the intervention group HbA1c and FPG improved significantly and in the control group FPG improved significantly and HbA1c did not. Patients' self-reported self-management activities improved significantly around blood glucose measurements (p<0.001) and physical exercising (p=0.001). Attitudes around the value of tight control of diabetes improved (p<0.001).

Conclusion: The findings suggest that community pharmacists in Libya may have the ability to improve type II diabetes care. The primary outcomes were not improved in intervention versus control. The before/after analysis showed significant improvement in primary outcomes in the intervention group and also in one of the primary outcomes in the control group. Patients' self-reported self-care activities and attitudes improved significantly in the intervention group.

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Even though, I have many difficulties that faced me during my PhD journey. I moved houses five times. I had a baby during my study. Beside all of that, I faced many difficulties to collect my data from Libya because the entire instability and security situation in Libya. I extended my study a year to enable collection of my data and have a chance to write my thesis. Without support from relatives, friends and my family I could not continue my study.

All my thanks go to the community pharmacists and patients with type II diabetes in Tripoli for their cooperation and support despite all of the instability in Libya. I would like to thank all my friends and relatives for help.

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Last but not least I would like to thank all of the staff who work in the Faculty of Life Sciences and School of Pharmacy & Medical Sciences.

Dedication

I would like to dedicate my thesis to my father, mother, husband and my lovely four children Fatma, Abdulrahman, Buthayna and Abdulrahim

Dissemination

Published work presented at the following conference:

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Glossary

FPG: Fasting Plasma Glucose

HbA1c: Glycated Hemoglobin

OGTT: Oral Glucose Tolerance Test

BMI: Body Mass Index

SIGN: Scottish Intercollegiate Guideline Network

ADA: American Diabetes Association

NHANES: National Health and Nutrition Examination Survey

WHO: World Health Organization

FINDRISC: Finnish Diabetes Risk Score

NHS: National Health Service

LADE: Libyan Association for Diabetes and Endocrinology

FDA: Food and Drug Administration

ADR: Adverse Drug Reaction

NSPSN: National Patient Safety Agency

LDCG: Libyan Diabetes Care Guideline

CLIs: Combined Lifestyle Interventions

SDT: Self-Determination Theory

PT: physical therapist

IPF: International Pharmaceutical Federation

PC: Pharmaceutical Care

TOFHLA: Test Of Functional Health Literacy in Adults

REALM: Rapid Estimate of Adult Literacy in Medicine

NVS: Newest Vital Sign

CSM: Common Sense Model

KAP: Knowledge Attitude and Practice

OPD: Out-Patient Department

DAS: Diabetes Attitude Scale

HCPs: Health Care Professionals

PSNC: Pharmaceutical Services Negotiating Committee

SPSS: Statistical Package for Social Sciences

CDCP: Centers for Disease Control and Prevention

MDRTC: Michigan Diabetes Research Training Center

OHMS: Oral Hypoglycemic Medicines

SOPs: Standard Operating Procedures

ANCP: Australian National Consensus Position

DKT: Diabetes knowledge test

ADKQ: Australian Diabetes Knowledge Questionnaire

MDKT: Michigan Diabetes Knowledge Test

CDEs: Certified Diabetes Educators

CE: Continuing Education

SDSCA: Summary of Diabetes Self-Care Activities

BG: Blood Glucose

GPP: Good Pharmacy Practice

MURs: Medicines Use Reviews

Introduction

The thesis is structured into eight chapters. **Chapter One** describes the health care system and diabetes care in Libya and summarises effective management of type II diabetes. **Chapter Two** provides the reader with the essential literature review. The aims and objectives of the thesis are outlined in **Chapter Three**. The structure of community pharmacy premises and pharmaceutical services in Tripoli, Libya are described in **Chapter Four**. Community pharmacists' knowledge and practice with respect to type II diabetes are explored in **Chapter Five**. Steps taken to enhance community pharmacists' diabetes knowledge (i.e. training) are outlined in **Chapter Six**. A randomized controlled trial of community pharmacy intervention to improve glycemic control for patients with type II diabetes is described in **Chapter Seven**. The discussion and conclusion along with suggestions for future studies are provided in **Chapter Eight.**

Chapter One is divided into five sections. A brief description of geography, demographics and diabetes care in Libya is provided in **Section 1.1**.The pathophysiology of type II diabetes along with incidence and prevalence are outlined in **Section 1.2.** The general management of type II diabetes is described in **Section 1.3.** Diabetes medicine management is outlined in **Section 1.4** and the chapter summary is provided in **Section 1.5.**

From the outset, it is important to define key terms related to clinical and self-management of patients with type II diabetes. Among the terms used in this document are: (medical) pathophysiological, incidence and prevalence terms; behavioural terms related to self-management; and medicines management including medicine adherence, patient counselling and health education.

1.1. Brief description of geography, demographics in Libya

In this section, important geographical information concerning Libya will be provided as this study concerns the improvement of medicines management for type II diabetes in Libya. It is important to explain to the reader where Libya is, and provide its demographic profile, because the number of Libyan people affected by diabetes is considered to be high. The most important information concerning the Libyan health care system will also be discussed. This context will help the reader to understand the research.

1.1.1. Geographic profile

Libya is an upper middle income North African nation located on the coast of the Mediterranean Sea. The country borders Algeria, Chad, Egypt, Niger, Sudan and Tunisia. Libya has a Mediterranean climate along the coast, which comprises four seasons, which are mainly dry and hot in summer and warm and rainy in winter, whilst the south of Libya has a semi-desert climate. The main cities are concentrated in the northern part of the country along the coastal area. **Figure 1.1** shows the geographic location of Libya (WHO, 2007).

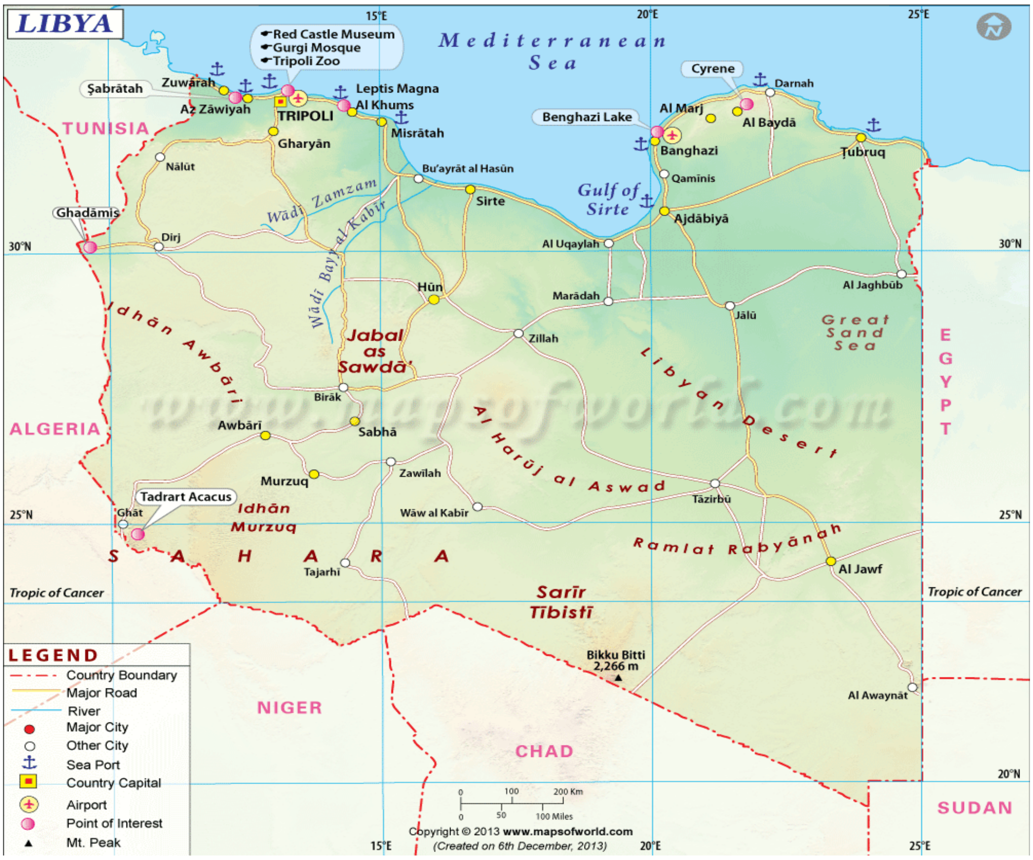


Figure 1.1: Geographical locations of Libya

Source: MAP XL copied from electronic source http://www.mapsofworld.com/libya/ 2002-2016

1.1.2. Population size

The total population of Libya in 2015 was 6,278,000 (WHO, 2017). It has one of the lowest (overall) population density rates in the world due to its large geographical area of 1,775,500 square kilometres. Most of the population lives in urban areas with about 85% concentrated in two main cities Tripoli and Benghazi and 15% living in rural areas (WHO, 2007).

1.1.3. Diabetes care in Libya

The incidence of diabetes has been increasing in recent years in Libya. There are some activities and interventions to reduce the cost of treatment. The

Libyan Association for Diabetes and Endocrinology (LADE) has different activities, has held conferences and publishes information to educate people with diabetes. The first publication of the Libyan Diabetes Care Guidelines (LDCG) was launched in 2010 and this guideline was launched at a conference held in Dat ElImad in Tripoli. Bishya (2010) stated that LADE was responsible for disseminating these guidelines amongst the front line workers as the first step towards implementation. It is noteworthy that most of the local nursing staff have a limited command of English; translation to Arabic will obviously enhance their involvement in implementing these guidelines. This process may even help patients understand “what care to expect”. This is an important advocacy role and highly appropriate for LADE to undertake. However, auditing of this guideline has still not emerged, and there is no on-going study to review this guideline.

A workshop titled Living with Diabetes was held in Sabratha Hall on April 2012. Sabratha is located on the Mediterranean coast about 66km west of Tripoli and it is famous for its historical heritage. The workshop was about improving self-management of diabetes for people with diabetes. In a two day programme, the first day consisted lectures given to physicians working in primary care and the second day comprised lectures about awareness and knowledge of diabetes especially for people with diabetes (LADE, 2012).

1.1.4. Diabetes pathway in Tripoli/Libya

The pathway begins when a patient describes symptoms of diabetes to their doctor. Next, blood samples are taken to the laboratory for analysis. The patient collects his/her results from the laboratory and returns back to the physician. The diagnostic criteria for diabetes are highlighted in **Table 1.1**. The medicines prescribed for the patients are dispensed by either the hospital pharmacist or community pharmacist. There is one special hospital for diabetes in Tripoli named National Centre for Diabetes & Endocrinology (NCDE). NCDE provides diabetes follow-up services at its outpatient clinics to patients with diabetes (Ashur et al., 2016). To have free of charge medicine patients with diabetes have to bring with them a diabetic card and receive their medicine from the NCDE hospital. The card holds personal information, type of diabetes, medicine information, and recommendations about self-management. The card is used to record medical follow-up (Ashur et al., 2015). The card is also used to identify that the patient has diabetes, if for instance the patient collapsed then people are better able to help the patient.

The management of diabetes has been highlighted in the LDCG (NDCGAB, 2010) by stating that patients with diabetes should be educated and supported therapeutically to control blood glucose. **Table 1.2** also describes the goals of blood glucose control to prevent microvascular complications.

The diabetes care plan has been explained in the LDCG by dividing it into initial visit and follow up care plan. In the initial visit the physician will take the medical history of patient including: symptoms of disease, eating habit, smoking status, lifestyle, any acute or chronic complications, and cardiovascular risk factors inherited, hypertension and dyslipidaemia, diabetes family history. Afterwards, a physical examination includes: height, weight, BMI, and waist circumference; blood pressure measurements systolic and diastolic; oral examination; cardiovascular evaluation; abdominal examination, including liver size; foot examination, for oedema, ulcer, deformities and footwear; neurological examination including vibration, reflexes, touch, monofilament and motor system. Next, the diagnostic tests are performed for blood glucose and HbA1c, serum creatinine and eGFR, lipid profile (total-, LDL-, HDL-cholesterol and triglycerides), urinalysis (microscopy, proteinuria, and microalbuminuria), thyroid stimulating hormone (for people with type I diabetes). Later, the treatment plan is discussed between patient and doctor in order to control blood glucose by lifestyle changes or by both taking medicine and lifestyle modification. In everyday practice referral of patients to a diabetes educator, dietician, foot care examination, eye examination, cardiologist, psychological assessment or family planning (for female in reproductive age) is uncommon. In an editorial, Benamer (2007) said he was shocked to see a Libyan patient come to the UK for treatment based on advice from his Libyan doctor. The patient did not carry with him any referral letter. He was just carrying with him different medications and some emptied containers of other medicines used.

For the follow up care plan, it has been recommended by LDCG that every visit should evaluate blood pressure, weight, blood glucose, medication review, smoking status, physical activity, diet review and foot care. In addition, HbA1c and lipid profile should be assessed every three to six months. As well as annual: fundus examination, feet examination including peripheral pulses sensation and feet inspection, cardiac symptoms, lipid profile, creatinine and eGFR, microalbuminuria, inspection of injection sites and oral examination, including gums (NDCGAB, 2010).

Table 1.1: Diagnostic criteria of diabetes

Source: (National Diabetes Care Guidelines Advisory Board, 2010).

	Normal	Impaired fasting glycaemia	Impaired glucose tolerance	Diabetes
Fasting plasma glucose (mg/dl	<110	110-125	<126	≥126
2-H plasma glucose (mg/dl)	<140	–	140-199	>200
Random plasma glucose (mg/dl)	–	–		>200 (plus symptoms)
An HbA1C greater than 6.5 % can be used to support diagnosis				

Table 1.2: Indicators used to manage hyperglycaemia

Indicator	Normal	Target	Action required
Plasma glucose values (mg/dl)			
Pre- meal and (fasting) glucose	<110	90-130	<90 or >150
Post- meal glucose	<120	110-150	<110 or >180
HbA1c%	<6,0	6.5-7.0	>7.0

1.1.5. Structure of the health care system in Libya

The Libyan government provides free health care to all citizens. The public sector is the main health service provider. Health care including preventive, curative and rehabilitation services are provided to all citizens free of charge by the public sector. Almost all levels of health services are decentralized. In Libya, there is a mixed system of public and private health care, rather than a purely state-run model. Health care is delivered through a series of primary health care units, centres, polyclinics, rehabilitation centres, general hospitals in urban and rural areas and tertiary care specialised hospitals (WHO, 2007). The health care delivery system operates on three levels. The first level comprises: the primary health care units (which provide curative and preventive services for 5.000 to 10.000 citizens); primary health care centres (serve from 10,000 to 26,000 citizens); and polyclinics, staffed by specialised physicians and containing laboratories as well as radiological services and a pharmacy. These polyclinics serve approximately 50,000 to 60,000 citizens. At the second level, there are general hospitals in rural and urban areas where care is provided to those referred from the first level. The third level comprises tertiary care specialized hospitals see **Figure 1.2.**

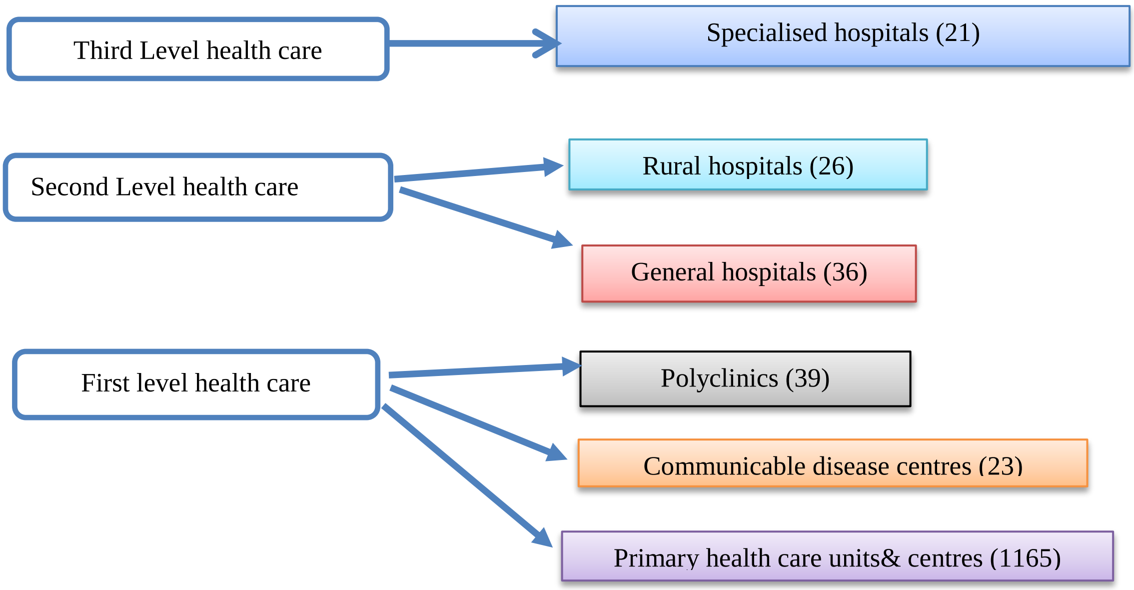


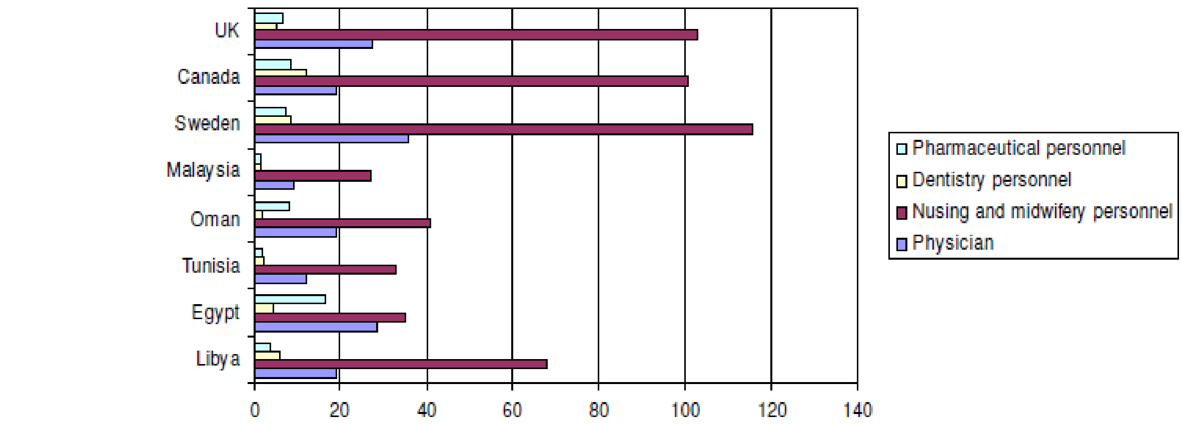
Figure 1.2: The levels of health care system delivery Source: WHO (2007)

1.1.6. Recent developments

Libya's health care system has deteriorated to the point of collapse and struggles to deal with casualties from the conflict. Serious illness and disease are rising. In conflict areas, over 60% of hospitals have been inaccessible or closed in the last six months, especially in the east and south (WHO, 2016). Hospitals are overcrowded, and their capacities have been severely reduced by a large scale exodus of foreign health workers (WHO, 2016). There is also a shortage of essential medicines and supplies. An estimated 1.9 million people need assistance to meet their basic health-care needs (WHO, 2016).

1.1.7. Human resources in the health sector

Human resource assessment, production and management are a high priority for the health sector. There are no clear plans to match needs with the number and categories of health personnel. The lack of an accreditation system, weak inter-sectional collaboration, lack of links between continuous medical education programmes and career development, and inadequate training in management are other factors that hinder health care delivery. In 2010 there were 19 physicians, 6 dentists, 3.6 pharmacists and 68 nurses and midwives per 10,000 population, see **Figure 1.3** for international comparisons.



	Libya	Egypt	Tunisia	Oman	Malaysia	Sweden	Canada	UK
Pharmaceutical personnel	3.6	16.7	2	8.1	1.7	7.3	8.3	6.6
Dentistry personnel	6	4.2	2.4	2	1.4	8.3	11.8	5.2
Nusing and midwifery personnel	68	35.2	32.8	41.1	27.3	115.7	100.5	103
Physician	19	28.3	11.9	19	9.4	35.8	19.1	27.4

Figure 1.3: International comparison of Libyan healthcare staffing (staff per 10,000 Population) Source: WHO (2011)

1.1.8. Communication in health

Information and communication technology (ICT) is increasingly recognised as an essential element to support health care services. ICT activities are isolated and uncoordinated, without adequate communication and consultation between the different on-going programmes (WHO, 2007). Awareness on ICT issues among staff is not optimal. This is largely the result of inadequate computer literacy among health professionals, many of whom have not had training or orientation in this field. In summary, health care informatics expertise is inadequate (WHO, 2007). The information and telecommunication infrastructure in health care institutions is weak (WHO, 2007). Most hospitals, primary health care centres, medical colleges and other health facilities do not have the necessary infrastructure to benefit from electronic-health solutions. For example, hospital and health facility records and information are not computerized (WHO, 2007).

1.1.9. Pharmaceutical structure

The basic structure of the pharmaceutical sector is predominantly public, with the Government aiming to provide medicines to all citizens. However, recently this may have changed because of the collapse of the health care system in the public sector. According to WHO (2007), the National Pharmaceutical and Medical Supplies Company are responsible for providing pharmaceutical supplies, centrally to both the public and private sectors. In addition, Libyan professionals are permitted to have agencies for the international pharmaceutical companies and are also able to bring medicines and supplies of international quality to both the public and private health sectors. There is no recent document describing the structure of the Libyan pharmaceutical services. El Oakley et al. (2013) highlighted the current inadequacy of the Libyan pharmaceutical sector and its deficient quality assurance systems. Drug legislation and regulation is inadequate, and there is no stable or functioning drug regulatory authority with adequate resources and infrastructure. It has been recommended that there is a need to implement modern legislation and regulation to circumvent the current supply difficulties and acute shortages (El Oakley et al., 2013).

1.2. Pathophysiology, incidence and prevalence of type II diabetes

This section discusses the pathophysiology, aetiology and prevalence of type II diabetes globally and in Libya. It aims to provide reader with background information about the scale of diabetes issues worldwide and projected growth in patient numbers.

1.2.1. What is type II diabetes?

Type II diabetes is a complex metabolic disorder that is characterized by hyperglycaemia and associated with a high risk of cardiovascular, microvascular, and other complications (Diabetes Care, 2015; International Diabetes Federation, 2015). Although glycaemic control is associated with reductions in the risk of microvascular complications, the macrovascular benefits of glycaemic control are less certain. Furthermore, concern has been raised about the cardiovascular safety of anti-hyperglycaemic therapies (Holman et al., 2014).

The imbalance between energy intake and expenditure is the most important underlying pathology and is regulated by complex interaction between multiple genes and environmental factors (Thomas & Vasan, 2016). The disease is most often suspected to be due to defects both at the level of insulin resistance and insulin secretion (Thomas & Vasan, 2016).

Two terms requiring definition are: glycosylated haemoglobin (HbA1c) and Fasting Plasma Glucose (FPG). In the term HbA1c, “glycation refers to non-enzymatic addition of sugar residue to an amino group of a protein” (Thomas & Vasan, 2016, p.25). HbA1c gives a retrospective index of integrated plasma glucose values over a 6 to 8 week period and is not subject to wide fluctuations in plasma levels. HbA1c serves as a reliable indicator of diabetes control during the past 90 days, effectivness of treatment and risk of development of acute or long-term complications. Hence, HbA1c should be performed routinely in all patients with diabetes, to assess the degree of glyceamic control at initial visit and then as a part of continuing visits every three months to assess metabolic control (Thomas & Vasan, 2016).

FPG is defined by the American Diabetes Assocaition (2016a) as the test checks on a person's fasting blood glucose levels. Fasting means not having had anything to eat or drink (except water) for at least 8 hours before the test. This test is usually done first thing in the morning, before breakfast. Diabetes is diagnosed at FPG of greater than or equal to 126 mg/dlmilligrams. The concordance between the FPG and 2-hour plasma gluscose (PG) tests is imperfect, as is the concordance between A1c and either glucose-based test. National Health and Nutrition Examination Survey (NHANES) data indicate that an A1c cut off point of ≥6.5% identifies one-third fewer cases of undiagnosed diabetes than a fasting glucose cut off point of ≥126 mg/dL (7.0 mmol/L) (Picón et al., 2012). Numerous studies have confirmed that, compared with these A1c and FPG cut off points, the 2-hour PG value diagnoses more people with diabetes. Of note, the lower sensitivity of A1c at the designated cut off point may be offset by the test's ease of use and facilitation of more widespread testing (American Diabetes Association, 2016a).

Unless there is a clear clinical diagnosis (e.g. a patient in a hyperglycaemic crisis or with classic symptoms of hyperglycaemia and a random plasma glucose ≥200 mg/dL), it is recommended that the same test be repeated immediately using a new blood sample for confirmation because there will be a greater likelihood of concurrence. For example, if the A1c is 7.0% and a repeat result is 6.8%, the diagnosis of diabetes is confirmed. If two different tests (such as A1c and FPG) are both above the diagnostic threshold, this also confirms the diagnosis. On the other hand, if a patient has discordant results from two different tests, then the test result that is above the diagnostic cut off point should be repeated. The diagnosis is made on the basis of the confirmed test. For example, if a patient meets the diabetes criterion of the A1c (two results ≥6.5%), but not FPG (<126 mg/dL [7.0 mmol/L]), that person should nevertheless be considered to have diabetes (American Diabetes Association, 2016a).

1.2.2. Complication of type II diabetes

Uncontrolled type II diabetes has serious health implications other than chronic hyperglycaemia, such as heart disease, stroke, retinopathy, neuropathy, and nephropathy (Matricciani and Jones, 2015). The complications do not end there; lower extremity amputations comprise over 60% of non-traumatic amputations in the United States (Neder and Nadash, 2003). Type II diabetes related lower extremity amputations have critical implications for individuals, family members, and caretakers in terms of psychosocial, physical, functional, and financial implications (Scollan-Koliopoulos, 2004). Type II diabetes related complications account for a death risk that is two times higher than that of someone that does not have type II diabetes (Centres for Disease Control and Prevention, 2011). However the development of such complications can be prevented and reduced through the implementation of comprehensive programs focused on foot care, which have been shown to greatly reduce amputation rates (Neder and Nadash, 2003).

Type II diabetes foot complications, which more often affect older adults, have the capacity to diminish a person's quality of life (Matricciani and Jones, 2015). Foot self-care behaviours, including daily inspection of feet, professional treatment, hygiene, and proper footwear help minimize the risk of foot complications (Matricciani and Jones, 2015). Type II diabetes is multifaceted and requires a multidisciplinary approach to the treatment of the condition and prevention of associated complications (Wu et al., 2007).

1.2.3. Risk factors of type II diabetes

Type II diabetes is caused by a combination of genetic and lifestyle factors (Kaprio et al., 1992). Beyond the genetic predisposition and increasing age as non-modifiable conditions, several somatic and behavioural risk factors have been identified in the development of type II diabetes mellitus, including obesity (Eckel et al., 2011), low physical activity (Sigal et al., 2006), smoking (Kowall et al., 2010) and hypertension (Meisinger et al., 2005). In addition, research has made great efforts to investigate whether psychosocial factors are related to the onset of type II diabetes. Recent studies found that depression (Knol et al., 2006, Mezuk et al., 2008) and post-traumatic stress disorders (Lukaschek et al., 2013) as well as burnout (Melamed et al., 2006), high job-strain (Norberg et al., 2007), sleep disorders (Frank and Durden, 2017) and perceived mental stress (Kato et al., 2009) are associated with an increased risk of type II diabetes.

There is also some preliminary evidence suggesting that social support has an impact on the subsequent development of type II diabetes. Studies showed that single indicators of social support such as low emotional support in women (Norberg et al., 2007) and living alone in men (Meisinger et al., 2009) are associated with an increased risk of type II diabetes. Social support refers to a coping resource provided by relationships with significant others including family members, friends, co-workers and club members. Two dimensions of social support should be distinguished, namely functional and structural support. Functional support refers to the aid and encouragement provided to the individual by the social network, whereas structural support describes the characteristics of the network of people surrounding an individual and his/her interactions within this network (Altevers et al., 2016).

Several dietary practices are linked to unhealthy body weight and/or type II diabetes risks, including high intake of saturated fatty acids, high total fat intake and inadequate consumption of dietary fibre (WHO, 2014). High intake of sugar-sweetened beverages, which contain considerable amounts of free sugars, increases the likelihood of being overweight or obese, particularly among children (Singh et al., 2013, Jeon and Murray, 2008). Recent evidence further suggests an association between high consumption of sugar-sweetened beverages and increased risk of type II diabetes (WHO, 2014, Lu et al., 2014, WHO, 2015).

1.2.4. Prevalence of type II diabetes

The number of people with diabetes is increasing due to: population growth; aging; urbanisation; and the increasing prevalence of both obesity and physical inactivity. In 2015, the number of people with diabetes reached 415 million adults and by 2040 the number will increase to 642 million people worldwide (International Diabetes Federation, 2015). The prevalence of diabetes in the Middle East and Northern African countries reached approximately 35.4 (24.3–47.4) million people, or 9.1% (6.3–12.2%) of adults aged 20-79. Over 40.6% of these are undiagnosed. Although only 54.9% of all adults in the region live in urban areas, 67.0% of people with diabetes live in urban environments. The vast majority (83.9%) of the people with diabetes in the region are living in low or middle income countries (International Diabetes Federation, 2015).

The International Diabetes Federation (2015) estimated that the prevalence of diabetes in Libya accounts for 9.2% of the population with uncertainty in the range 6.4% to 11.9%. However, it is expected that the true incidence is higher than that suggested by the statistics. In 2009 the survey done on 3625 participants by using the STEPwise accounted that 16.4% from the participants have diabetes (Beshyah, 2010).

It has been defined by WHO (2016, p: 1) as "*a simple, standardized method for collecting, analysing and disseminating data in WHO member countries*". Then the surveyed data was compared with the (other) Middle Eastern and North African countries (see **Table 1.3**) (Beshyah, 2010).

Table 1.3: Comparison of STEP wise survey data generated from 10 Middle Eastern and South African countries to show the frequency of non-communicable diseases. Source: (Beshyah, 2010).

Country	Year	Diabetes %	Hyper-tension (%)	Overweight & Obesity (%)	Hyper-cholesterolemia (%)	Smoking (%)	Low Physical activity (%)	Low intake of fresh fruits& vegetables (%)
		FBG≥7 mmol/dl	BP≥140/90 mmHg	BMI≥25	Cholesterol level≥5.2mmol/dl	Current daily smokers	Daily activity≥10min	≤5 serving /day
Syria	2003	20.5	28.4	56.3	34	24.7	31.15	95.7
Iraq	2005	10.4	40.4	66.9	37.5	21.6	56.7	91.4
Kuwait	2006	12.4	20.5	75.4	38.6	20.6	64.7	81
Sudan	2005	19.2	23.6	53.9	19.8	12	86.8	
Iran	2005	10.3	14.8	42.8	43.6	13	67.5	
Egypt	2005-2006	15.8	26.7	66	19.4	18	70.4	79
Jordan	2007	12	26	57	46	25	51	84
Saudi Arabia	2007	18.3	21.3	68.8	19.15	11	67.7	93.45
Libya	2009	16.4	40.6	63.5	20.9	49.6	43.9	34

1.2.5. Diagnosis of type II diabetes

Diagnosis of diabetes is based upon plasma glucose levels. Three ways to test diabetes are possible and each, in the absence of unequivocal hyperglycaemia, must be confirmed, on a subsequent day (Thomas & Vasan, 2016). The 75 g oral glucose tolerance test (OGTT) is more sensitive and modestly more specific than fasting plasma glucose (FPG) in the diagnosis of diabetes, but is poorly reproducible (Thomas & Vasan, 2016). Because of its ease, patient acceptability and lower cost, measurement of FPG is the preferred diagnostic test (Thomas & Vasan, 2016). The use of the glycosylated haemoglobin (HbA1c) for the diagnosis of diabetes was previously not recommended due to lack of global standardisation and uncertainty about diagnostic thresholds (Thomas & Vasan, 2016). Presently, because of a worldwide move towards a standardized assay and with increasing evidence about the prognostic significance of HbA1c it is being more widely used (Thomas & Vasan, 2016).

Approximately one-quarter of people with diabetes in the U.S. and nearly half of Asian and Hispanic Americans with diabetes are undiagnosed (Menke et al., 2015). Although screening of asymptomatic individuals to identify those with prediabetes or diabetes might seem reasonable, rigorous clinical trials to prove the effectiveness of such screening have not been conducted and are unlikely to occur (American Diabetes Association, 2016a). A large European randomized controlled trial compared the impact of screening for diabetes and intensive multifactorial intervention with that of screening and routine care (Griffin et al., 2011). General practice patients between the ages of 40–69 years were screened for diabetes and randomly assigned by practice to intensive treatment of multiple risk factors or routine diabetes care. After 5.3 years of follow-up, cardiovascular disease (CVD) risk factors were modestly but significantly improved with intensive treatment compared with routine care, but the incidence of first CVD events or mortality was not significantly different between the groups (Griffin et al., 2011). The excellent care provided to patients in the routine care group and the lack of an unscreened control arm limited the authors' ability to prove that screening and early intensive treatment impact outcomes (American Diabetes Association, 2016a).

1.2.6. Screening of diabetes

There is a major distinction between diagnostic testing and screening. When an individual exhibits symptoms or signs of the disease, diagnostic tests are performed and such tests do not represent screening (Engelgau et al., 2000). Screening may use a variety of methods (e.g. risk assessment questionnaires, portable capillary blood assessments, and laboratory-based assessments) and various thresholds or cut off points. In general, though, a screening test is not part of the diagnostic test. Ideally, screening tests are rapid, simple, and safe (Engelgau et al., 2000) A positive screening test only means the subject is more likely to have the disease than a subject with a negative screening test (Engelgau et al., 2000) . Separate diagnostic tests using standard criteria are required after positive screening tests to establish a definitive diagnosis (Gavin III et al., 1997).

Another screening method used in Finland is called the Finnish diabetes risk score (FINDRISC) and has proven its value in the national type II diabetes prevention programme in Finland, which was developed based on prospective data on the incidence of type II diabetes in a population-based cohort (Saaristo et al., 2007). The risk score consists of eight non-invasive variables, which can be self-reported. The FINDRISC questionnaire is the most widely used and tested diabetes risk score and has been validated in several European countries including Sweden, the Netherlands, Greece, Spain, Hungary and Germany (Alssema et al., 2008; Hellgren et al., 2012; Li et al.,2009; Makrilakis et al., 2011; Soriguer et al., 2012; Winkler et al., 2013). Although people who are obese or overweight are at great risk of developing type II diabetes, not every subject develops diabetes (Meijnikman et al., 2016).

1.3. General diabetes management

The current study focuses on two aspects of diabetes management: self-management (i.e. how people manage everyday life in terms of diet, exercise, feet care, eye care) and medicines management (i.e. oral hypoglycaemic adherence). In the long term, diabetes cannot be managed by medicine or diet alone, but when first diagnosed type II diabetes can be managed by diet and exercise. However, older people have to take oral hypoglycaemic tablets to control blood glucose levels, and may progress to management with insulin.

Keenan (2010) highlighted that recently diagnosed type II diabetes is initially managed by a combination of: restricted energy and carbohydrate intake; and an increase in physical activity. This should be incorporated into a structured education programme that is tailored to the patient’s particular needs and preferences. Funnell et al (2009:87) agree and stated that: “Diabetes self-management education (DSME) is a critical element of care for all people with diabetes and is necessary in order to improve patient outcomes.” Mehuys et al (2008) stated that community pharmacists can play a valuable role in the education of patients with diabetes, as they have the advantages of the ease of patient access (near homes and workplaces) and frequent patient contact due to collection of repeat prescriptions. I strongly agree that the pharmacist is easily accessible.

1.3.1. Diabetes Self-management

Self-management has become a popular term for behavioural interventions as well as for healthy behaviours (Lorig and Holman, 2003). This is especially true for the management of chronic conditions (Lorig and Holman, 2003).

Diabetes self-management is defined by Diabetes UK (2009: 3) as:

> "Self-management means that people have to make choices and decisions about how to manage their life and their diabetes. Through good self-management, people with diabetes can improve their quality of life and reduce the risk of developing complications. It can also help to prevent hospital admissions, or make those times when they do need to go into hospital, for whatever reason, a better experience, with a reduced length of stay."

Anderson & Funnel (2005:13) stated that:

> "The cornerstone of the empowerment approach is recognizing that the person with diabetes is completely responsible for managing his or her illness. The patient's responsibility is non-negotiable, indivisible, and inescapable. Although that statement may sound strong, we believe it is a straight forwards description of the reality of diabetes care. The patient's

> complete responsibility rests on three characteristics of the disease – choices, control, and consequences.”

This is particularly true when the self-management plan has been designed to fit patients’ diabetes, but has not been tailored to fit their priorities, goals, resources, culture, and lifestyle.

To manage diabetes successfully, patients must be able to set goals and make frequent daily decisions that are both effective and fit their values and lifestyles, while taking into account multiple physiological and personal psychosocial factors. Intervention strategies that enable patients to make decisions about goals, therapeutic options, and self-care behaviours and to assume responsibility for daily diabetes care are effective in helping patients care for themselves (Funnel & Anderson, 2004). There are some identified essential elements of diabetes self-management that people with diabetes need to be able to access and a minimum service level that needs to be in place to ensure that people are supported to self-manage (Funnel & Anderson, 2004).

Diabetes self-management includes eating healthy meals, exercising, monitoring blood glucose levels, taking medications, understanding psychological aspects of living with diabetes, using problem-solving skills to manage diabetes-related self-care challenges, and lessening risks of complications (Haas et al., 2013). Literature suggests lessening barriers is essential to diabetes self-management (Jones et al., 2014). Major barriers include an inadequate health system and communication interfaces, difficulty coping with diabetes, and managing diabetes within current social roles and context (Grant and Steadman, 2016).

Individuals also report experiencing a variety of emotional responses to a diagnosis of type II diabetes, including denial and fear of diabetes and resulting complications (Jones et al., 2014). Clients who reject their diagnoses of diabetes may feel “betrayed” by their own bodies and lose confidence in their abilities to implement therapeutic self-care behaviours. This fear and inability to accept diabetes is significant, commonly resulting in clients ignoring health care providers’ suggestions regarding how to successfully manage type II diabetes (Majeed-Ariss et al., 2015). These feelings are also influenced by depression and other negative emotions. In a cross-sectional survey of 160 rural African American women with type II diabetes, 70% had scores suggestive of significant depressive symptomatology (Miller, 2011). An open-ended survey and thematic qualitative analysis of data from 7,228 individuals with type II diabetes, of whom 1,050 lived in rural areas, almost 500 respondents reported emotional reactions such as not accepting the diagnosis of diabetes, anxiety, fear, and depression (Stuckey et al., 2014).

1.3.2. Lifestyle management

A healthy lifestyle has been defined by the National Institute for Health and Care Excellence (NICE 2015a) as one which involves being active, losing weight if one is overweight, getting enough exercise, having a healthy diet, not smoking and controlling alcohol intake. A doctor or nurse can provide people at risk with more information about a healthy lifestyle and what steps can be taken to keep type II diabetes under control (for example, having a healthy diet, taking more exercise and losing weight).

The components of lifestyle management were categorized by the Scottish Intercollegiate Guidelines Network (SIGN, 2013) into:

- Delivery of lifestyle interventions,
- Structured education,
- Self-monitoring of glycaemic control, and,
    - Smoking,
    - Obesity,
    - Physical activity,
    - Healthy eating

1.3.2.1. Diet management

It has been recommended by NICE (2015a) that having a healthy diet is an important part of living with type II diabetes. Eating healthily and losing weight, if the patient is overweight, help to manage diabetes better. If the patient is overweight, he or she will be encouraged to lose weight and agree on a target weight loss. It recommended by NICE (2015a) that the weight-loss target should be to lose 5% to 10% of body weight. Any weight loss will help, although the nearer the patient gets to a healthy body weight, the better it will be for the diabetic patient's long-term health. In recent decades, men and women around the globe have gained weight, largely due to changes in dietary patterns and decreased physical activity levels (Ezzati and Riboli, 2013). Excess adiposity reflected by higher body mass index (BMI) is the strongest risk factor for diabetes, and Asians tend to develop diabetes at a much lower BMI than those of European ethnicity (Hu, 2008).

Worldwide, an unhealthy lifestyle is one of the leading causes of preventable death (Lopez et al., 2006). Inactive lifestyle and obesity are highly associated with the risk of developing type II diabetes and the complications associated with this disease (American Diabetes Association, 2002, Mokdad et al., 2003).

Many programmes to improve physical activity and dietary behaviour have been investigated. Randomised controlled trials have shown positive effects of combined lifestyle interventions on the development of type II diabetes in patients with impaired glucose tolerance (Gillies et al., 2007).

In patients who already have type II diabetes, combined lifestyle interventions improved weight loss, diabetes control and lowering cardiovascular risk factors have proven to be effective (Espeland, 2007). The translation of these combined lifestyle interventions in community and primary care settings has been shown to be promising, yet challenging (Absetz et al., 2007) (Laatikainen et al., 2007). In addition, the effects of exercise-only programmes for patients with type II diabetes were small, even in randomised trial settings (Boulé et al., 2001, Thomas et al., 2006). Furthermore, when investigated in primary care, lifestyle counselling interventions had marginal effects on cardiovascular risk (Fleming and Godwin, 2008), exercise-referral schemes showed a small increase in physical activity in adults (Williams et al., 2007) and group education for patients with type II diabetes had modest effects on weight loss and smoking cessation (Davies et al., 2008).

1.3.2.2. Exercising and physical activity

Exercise is defined by SIGN (2013, p: 17) as “a subset of physical activity which is done with the goal of enhancing or maintaining an aspect of fitness (e.g. aerobic, strength, flexibility, balance). It is often supervised (e.g. in a class). Systematic and regular exercising is encouraged (e.g. jogging, swimming, attending exercise classes)”. However, physical activity is defined “*as any skeletal muscle movement which expends energy beyond resting level (e.g. walking, gardening, stair climbing)*” (SIGN, 2013, p: 17).

There are three general types of exercise: aerobic, resistance and flexibility. Aerobic exercise involves repeated and continuous movement of large muscle groups (Department of Health and Human Services, 2008). Activities such as walking, cycling, jogging, and swimming rely primarily on aerobic energy-producing systems. Resistance (strength) training includes exercises with free weights, weight machines, body weight, or elastic resistance bands. Flexibility exercises improve the range of motion around joints (Herriott et al., 2004). Balance exercises benefit gait and prevent falls (Morrison et al., 2010). Activities like tai chi and yoga combine flexibility, balance, and resistance activities (Colberg et al., 2016).

For many years, exercise along with diet and medication has been considered one of three cornerstones of diabetes therapy (Joslin et al., 1959). Regular physical activity is recommended for patients with type II diabetes since it may have beneficial effects on metabolic risk factors for the development of diabetic complications (ADA, 2002, ADA, 1997). The low-cost, non-pharmacological nature of physical activity further enhances its therapeutic appeal (Boulé et al., 2001).

The adoption and maintenance of physical activity are critical foci for blood glucose management and overall health in individuals with diabetes and prediabetes (Colberg et al., 2016). Physical activity includes all movement that increases energy use, whereas exercise is planned, structured physical activity. Exercise improves blood glucose control in type II diabetes, reduces cardiovascular risk factors, contributes to weight loss, and improves well-being (Chen et al., 2015, Lin et al., 2015). Regular exercise may prevent or delay the onset of type II diabetes development (Schellenberg et al., 2013). Regular exercise also has considerable health benefits for people with type I diabetes (e.g., improved cardiovascular fitness, muscle strength, insulin sensitivity, etc.) (Yardley et al., 2014). The challenges related to blood glucose management vary with diabetes type, activity type, and presence of diabetes-related complications (American Diabetes Association, 2016b, American Diabetes Association, 2016c). Physical activity and exercise recommendations, therefore, should be tailored to meet the specific needs of each individual (Colberg et al., 2016).

1.3.2.3. Structured education

Diabetes education courses provide information on how to manage diabetes through diet, physical activity and medication. They are run by health professionals – usually a diabetes specialist nurse or dietitian often in a group setting (NHS, 2015a). Structured education programmes for people with type II diabetes are an effective and cost efficient way of improving outcomes and are a key part of diabetes self-management when linked with collaborative care planning, screening and medications (NHS, 2015a, Deakin et al., 2006).

Acting early to prevent complications limits the impact on the person's life and saves the NHS money (Deakin et al., 2006). However access to structured education is very poor and there is an unacceptable variation in some areas, for example South London (Gadsby and Young, 2013). When people are diagnosed with diabetes, providers, referrers and commissioners work collaboratively so that real change can happen allowing education to reach a greater number of the population, as has been demonstrated by Bexley, Southwark and Lambeth (Cotter and Grumitt, 2011; Diabetes Modernisation Initiative, 2014). NICE states that structured education should be offered to every person with diabetes and/or their carer around the time of diagnosis, with annual reinforcement and opportunities taken to repeat education as necessary (NICE, 2011). It is vital to record and report those who are not attending the structured education offered (usually DESMOND or X-PERT) and provide a suitable alternative that meets their individual needs (NHS, 2015a; Department of Health and Diabetes UK, 2005). High quality alternative education programmes do exist for harder to reach groups and innovative ways should be sought to allow people with diabetes to access different types of learning (NHS, 2015b).

1.3.3. Pharmacological management

To treat type II diabetes, the commonly used oral therapeutics include sulfonylureas, biguanides, α-glucosidase inhibitors, thiazolidinedione, which often failed to protect the pancreas or control the disease progression accompanied by serious side effects (Minshall et al., 2008). Although the majority of patients with type II diabetes requiring insulin therapy can be successfully treated with basal insulin alone, some, because of progressive diminution in their insulin secretory capacity, will require prandial insulin therapy with shorter-acting insulins (Inzucchi et al., 2012). This is typically provided in the form of the rapid insulin analogues, insulin lispro (B28Lys,B29Pro human insulin), insulin as part (B28Asp human insulin) or insulin glulisine (B3Lys, B29Glu human insulin), which may be dosed just before the meal (Inzucchi et al., 2012). They result in better postprandial glucose control than the less costly human regular insulin, whose pharmacokinetic profile makes it less attractive in this setting. Ideally, an insulin treatment programme should be designed specifically for an individual patient, to match the supply of insulin to his or her dietary/exercise habits and prevailing glucose trends, as revealed through self-monitoring (Inzucchi et al., 2012). Since currently available medications cannot completely meet the clinical needs of type II diabetes treatment, scientists have been committed to the discovery and development of novel antidiabetic therapeutics (Hu et al., 2016).

The immediate purpose of lowering blood glucose is to provide relief from symptoms (thirst, polyuria, nocturia, and blurred vision). Thereafter, the aim is to prevent microvascular complications: loss of vision (retinopathy), renal failure (nephropathy), and foot ulceration (neuropathy). High blood glucose (hyperglycaemia) is also one of the features of diabetes – with raised blood pressure and cholesterol associated with macrovascular complications (myocardial infarction, stroke, and peripheral arterial disease). The effects of glucose-lowering therapies on cardiovascular morbidity and mortality are therefore of major importance and not necessarily related to glucose-lowering (SIGN, 20103).

It has been recommended that in the therapeutic management of hyperglycaemia when HbA1c >6.5% antidiabetic drugs are commenced and the therapy should be intensified if HbA1c > 7.5%. These targets are generalised and may be altered depending on individual circumstances (Keenan, 2010).

1.4. Diabetes medicine management

There is no widely accepted definition of medicines management, although the term is widely used. The National Prescribing Centre in England defines it as ‘a system of processes and behaviours that determines how medicines are used by patients and by the NHS’ (NHS, 2016). When first described in 2002, medicines management encompassed clinical assessment, monitoring and review in individual patients, medicines delivery services, review of repeat prescribing systems, clinical audit, health education, risk assessment, disease prevention and formularies and guidelines (Krska and Godman, 2011). Recent developments in the UK have resulted in considerable changes in the ways medicines are used; hence medicines management has also changed (Krska & Godman, 2011). These important developments include non-medical prescribing, increasing clinical roles of community pharmacists, changes in the way that GPs and pharmacists are remunerated for their NHS work, electronic prescribing, early discharge from hospital, hospital at home services, minor ailments services, pharmacy public health services and more standards for care quality (Krska & Godman, 2011)

The US Food and Drug Administration (FDA) reported in 1987 that 12,000 deaths and 15.000 hospitalizations were due to adverse drug reactions (ADRs) (Manasse, 1989a, Manasse, 1989b). The philosophy of Hepler and Strand (1990: 533) states that:

> "Drug related morbidity often preventable and pharmaceutical services can reduce the number of ADRs, the length of hospital stays, and the cost of care. Pharmacists must abandon factionalism and adopt patient-centred pharmaceutical care as their philosophy of practice."

This philosophy faces a variety of problems with its application but leads to development (in conjunction with other practitioners) of a practice of pharmaceutical care.

There is a debate about whether the terms pharmaceutical care or medicines management is the more appropriate term to use. Some British pharmacists argue that pharmaceutical care is used to describe only a particular model of practice so they are unhappy to use the term more generally. The term medicines management is widely used in NHS documents and has also gained favour in the UK among pharmacy managers. Medicines management encompasses all the activities that contribute to safe and rational medicine use, including strategic functions such as purchasing, formulary policy, risk management and many other roles of pharmacists and pharmacy technicians (Sexton et al., 2006).

1.4.1. Health education

Health education is defined by WHO (1998: 4) as:

> “Health education comprises consciously constructed opportunities for learning involving some form of communication designed to improve health literacy, including improving knowledge, and developing life skills which are conducive to individual and community health”

Although no figures are available, health literacy and numeracy are low in Libya. Since people with low health literacy have poorer health than those with adequate health literacy, improving health literacy is an important factor in reducing health inequalities (Anderson & Blenkinsopp, 2011). Health education is not only concerned with the communication of information, but also with fostering the motivation, skills and confidence (self-efficacy) necessary to take action to improve health (Anderson & Blenkinsopp, 2011).

1.4.2. Safe and effective use of medicine

Reporting errors is a vital part of every health professional's job and the UK's National Patient Safety Agency (NPSA) reporting and learning service (now the responsibility of NHS Improvement) encouraged this (Knapp et al., 2011). Research undertaken in 2005 showed that both pharmacists and support staff were, however, very unlikely to report incidents to the NPSA or even within the pharmacy (Ashcroft et al., 2005). Managing risk often involves changing procedures. This may be very simple or require extensive collaborative work. Simple solutions to reduce errors resulting from products with similar names or packaging could be placing them in different locations within the dispensary, or putting up warning signs indicating products should be double checked before dispensing (Knapp, et al., 2011). When patients move from one health care setting to another, or between health care and other settings, information about their medicines needs to move with them. There are many situations when these dos not occur and a proportion of these can result in harm (Krska & Godman, 2011).

1.4.3. Medicine adherence

Adherence to therapies is a primary determinant of treatment success. Failure to adhere is a serious problem, which not only affects the patient but also the health care system. Adherence to a medication regimen is generally defined as the extent to which patients take medications as prescribed by their health care providers (Osterberg & Blaschke, 2005). Another definition of medicine adherence existing in a WHO (2003) document adopted from Haynes and Rand is "the extent to which a person's behaviour – taking medication, following a diet, and/or executing lifestyle changes, corresponds with agreed recommendations from a health care provider". It includes the initiation of the treatment, implementation of the prescribed regime, and discontinuation of the pharmacotherapy (Vrijens et al., 2012). Adherence in diabetes can defined as "the active, voluntary involvement of the patient in the management of his or her disease, by following a mutually agreed course of treatment and sharing responsibility between the patient and health care providers" (Barofsky, 1978). The word "adherence" is preferred by many health care providers, because "compliance" suggests that the patient is passively following the doctor's orders and that the treatment plan is not based on a therapeutic alliance or contract established between the patient and the physician (Osterberg & Blaschke, 2005).

Meanwhile, some studies classify adherence as either primary or secondary. Primary nonadherence is the frequency with which patients fail to fill prescriptions when new medications are started so it is related to refilling and initiation of the medication therapy (Fischer et al., 2010). Secondary nonadherence is defined as the medication being not taken as prescribed when prescriptions are filled. It does not only affect the clinical outcome but also affect the financial outcome of the health system (Solomon and Majumdar, 2010). Various methods have been reported and are in use to measure adherence. The methods available for measuring adherence can be broken down into direct and indirect methods of measurement. Direct methods include direct observed therapy, measurement of the level of a drug or its metabolite in blood or urine and detection or measurement of a biological marker added to the drug formulation, in the blood. Direct approaches are one of the most accurate methods of measuring adherence but are expensive. Moreover, variations in metabolism and "white coat adherence" can give a false impression of adherence (Osterberg and Blaschke, 2005). Indirect methods include patient questionnaires, patient self-reports, pill counts, rates of prescription refills, assessment of patient's clinical response, electronic medication monitors, measurement of physiologic markers, as well as patient diaries. Each method has its own advantages and disadvantages and no method is considered as the gold standard (Wagner et al., 2001, Alcoba et al., 2003).

Diabetes is further complicated by a multitude of other factors, such as, the 'chronic' nature of the disease, lifelong requirement for medications, requirement for changes in lifestyle, and the need to cope with social, cultural and psychological distress that may occur with the disease. In the midst of such complexities, remaining adherent to treatment recommendations may be a challenge (Lerman, 2005). Treatment adherence, in the context of diabetes, covers adherence to an array of self-care behaviours, constituting home glucose monitoring, adjustment of food intake, and administration of medication, regular physical exercise, foot care and regular medical visits (Sabatae, 2003). Although adherence to each self-care measure contributes to the effective management of diabetes (Sapkota et al., 2015). Adherence rates are typically higher among patients with acute conditions, as compared with those with chronic conditions (Jackevicius & Mamdani, 2002; Haynes & McDonald 2002). Adherence to oral hypoglycaemic medications in patients with T2D is 36 to 93% and to insulin is 63% (Crsmer, 2004). The low level of medication adherence is likely to be one of the major factors contributing to sub-optimally controlled diabetes (Bailey and Kodack, 2011, Rhee et al., 2005).

1.4.4. Patient counselling

‘Patient counselling’ is the term employed by the pharmacy profession to describe the verbal activities that constitute the extended role (Pilnick, 2003). In practice, it ranges from simply stating the dosage of a drug as it is handed over to the client, through counter prescribing for common ailments, to giving advice with regard to lifestyle and health promotion issues, like smoking cessation, cholesterol testing and contraception (Pilnick, 2003). Patient counselling has a central part to play in the ‘extended role’, which is seen as the way forward for the profession (RPSGB, 1996). Through counselling, it is hoped both that clients will be equipped with the resources to use any medications more safely and effectively, and that the perception of the pharmacist as the ‘first port of call’ for general advice on medicines and health will become commonplace (Pilnick, 2003).

Counselling involves helping some to explore a problem and to identify conflicting issues so that they can decide for themselves what to do. In other words this involves helping people to help themselves.

1.5. Chapter summary

Type II diabetes has become a global epidemic. Type II diabetes is associated with more than a twofold excess mortality from cardiovascular disease, devastating microvascular complications affecting the eyes, kidneys and nerves, as well as with significant comorbidities including cancer, infections and psychosocial stress. If left untreated, the microvascular complications will ultimately lead to blindness, overt kidney failure, foot ulcers and amputations. There is an enormous challenge for society and the health care system to organise treatment and management for people with diabetes to reduce its serious impact on the health of the individual, as well as to reduce the otherwise extreme expenditure (for example, to compensate for lost working years as well as for managing blindness, dialysis, and amputations and so on). Many landmark achievements within diabetes care have been obtained during recent years, including definitive knowledge that multifactorial pharmacological as well as non-pharmacological intervention targeting physical inactivity, smoking, reduction of blood pressure and lipids, as well as lowering glucose, significantly improve the most important clinical outcome variable in people with diabetes (Thomas, et al., 2016).

Pharmacists have an important role to play in the care of patients with diabetes. The goal of pharmaceutical care is to ensure that patients make the best use of their medications and achieve the desired therapeutic outcomes. Pharmacists in an ambulatory care setting have an excellent opportunity to educate patients about diabetes and its complications, proper self-management, and the correct use of medications and self-care devices.

In **Chapter Two** the practice and concepts of pharmaceutical care will be reviewed in detail.

Literature Review

This chapter describes the scope of knowledge and practice with respect to type II diabetes among patients and community pharmacists. The overall goals of this chapter were firstly to establish the significance of the general field of study, and secondly to identify a place where a new contribution could be made. The bulk of the chapter critically evaluates the different research methodologies used in this field in order to identify the appropriate approach for investigating the research question(s).

The chapter is structured into five sections. **Section 2.1** highlights methods of literature review applied in the current thesis. The management of type II diabetes including self-management and theories related to self-efficacy are highlighted in **Section 2.2**. An overview of pharmacy practice is provided in **Section 2.3** including pharmaceutical care or medicine management relating to type II diabetes management and the accessibility of community pharmacists. Diabetes health literacy along with the impact of type II diabetes knowledge, practice and attitudes in patients and pharmacists is outlined in **Section 2.4**. The chapter summary is in **Section 2.5.** Aims and objectives relating to the knowledge gap identified in the literature review are then stated in **Chapter 3.**

Two kinds of literature review were carried out (scoping and systematic) to (a) provide a clear picture of the management of type II diabetes in practice and (b) identify specific evidence for the role of the community pharmacist in diabetes management.

The specific objectives of this chapter are to:

- Identify the standard of care for management of type II diabetes.

- Establish the effectiveness of community pharmacists' type II diabetes care by assessing high quality randomised controlled clinical trials.
- Recognise any social and behavioural issues related to type II diabetes self-management (for example: self-care behaviours, empowerment, and health beliefs).

More broadly, the literature review explored ideas and themes around:

- the effectiveness of diabetes self-management
- the effectiveness of community pharmacists' roles in relation to diabetes management
- comparing and contrasting comprehensive diabetes management guidelines from a developed (SIGN) and less developed (LDCG) healthcare economy.

2.1. Methods

In the current study, both scoping and systematic review were conducted to identify gaps in knowledge and critically analyse studies meeting specific criteria (by systematic review). The systematic review focuses on community pharmacist interventions in type II diabetes management. However, the scoping review focuses on broader topics of importance to the thesis such as: medication adherence; pharmacist and patient diabetes knowledge; health literacy; self-efficacy etc.

The scoping review was completed by searching in different databases Medline, PubMed, Science Direct and Wiley online library. The key words were: type II diabetes management, diabetes health literacy, patient counselling, patient empowerment, and diabetes knowledge. The literature review adopted in this research is centred on generating information relevant to the current study themes. The most well-known method for conducting a systematic review is produced by the Cochrane collaboration (Aveyard, 2007). For this reason, the Cochrane library and policy document guidelines were used to guide the search for and evaluation of relevant high-quality literature.

A systematic search was carried out in five electronic databases (Medline, Embase, Scopus, Cochrane Library and Web of Science) with the help from a subject specialist librarian. The publications were searched from 2011 to 2017. The search terms used included medical subjects headings and text terms combined with Boolean operators. The detailed search strategy used for each database is provided in **Appendices 1** to **5**.

Studies were included in the review if they were randomised controlled trials or cluster- randomised controlled trials evaluating the effectiveness of interventions delivered only by community pharmacists and directed at patients with type II diabetes in comparison with usual care. Studies that took place in hospital or outpatient primary care were excluded (see **Figure 2.1**). Studies were included if they reported one or more of the following outcomes: HbA1c, and blood glucose (FPG). The risk of bias in included studies was assessed by using the Cochrane risk of bias tool.

The researcher extracted and screened all the data received from the electronic databases using the pre-specified inclusion criteria. Then, the abstracts screened for the specific inclusion criteria after that the full text articles were screened carefully. The excluded and included studies were sent to a supervisor to review. Data was extracted from included studies using Microsoft

Word. The data extracted from each study included authors, publication year, study design, setting and country where the study took place, sample size, patient age and gender, follow-up duration, details of pharmacist intervention and control as well the pharmacist training and study primary and secondary outcomes (**see Tables 2.1** and **2.2**). This review summarised data for the outcome measures HbA1c and FPG. The results are reported as baseline, follow up and p-value for both control and intervention groups (see **Table 2.3**).

Risk of bias was assessed by using the Cochrane of risk bias tool (Higgins et al., 2011). The risk of bias in each study was assessed according to the following criteria: suitability of random sequence generation, concealment of allocation, blinding of outcome assessment, completeness of outcome data, selective outcome reporting, and other sources of bias. Each risk of bias item was rated as "low risk" if it was unlikely that a bias would seriously alter the results; "unclear" if it was likely that a bias would raise some doubt about the results; or "high risk" if it was likely that a bias would seriously alter the results.

2.1.1. Justifying the methodology of literature review

The literature review is a fundamental source of information and without it the study should not be conducted because the gap in knowledge would not be clear. Therefore, comprehensive literature review is considered to be essential for understanding the accumulated knowledge about the topic being reviewed (Garrard, 2007). A literature review uses as its database primary or original scholarship, and does not report new primary scholarship itself. Systematic review strives to identify all the information available on a topic, whilst describing a clear, comprehensive (search and evaluation) methodology. Systematic reviews take a highly structured approach, aiming to minimise the effect of biases and random errors in conclusions (Bowling, 2014). They include information on materials and methods in relation to the published and unpublished literature (Chalmers and Altman, 1995). In quantitative research, systematic reviews are mostly based on Randomised Controlled Trials RCTs, but do include information derived from other designs when appropriate (Bowling, 2014). One of the main features of systematic review is that reviewers follow a strict protocol to ensure that the review process undertaken is robust by using explicit and rigorous methods to identify, critically appraise, and synthesis relevant studies in order to answer a predefined question. The reviewers then develop a comprehensive searching strategy, and leave no stone unturned in the search for relevant literature, and do not regard the process complete until the search is exhausted.

The reasons for choosing two types of review were:

- the systematic review enables the reader to appraise critically the most robust evidence available in an attempt to synthesize what is known, and not known, about the efficacy of particular interventions.
- systematic review aims to answer a particular question or test a hypothesis (when this can be specified) usually in relation to a particular health care intervention on a particular population group.
- systematic reviews place an emphasis on judging the quality of evidence.
- a scoping study tends to address broader topics where many different study designs might be applicable (Arksey and O'Malley, 2005).

- a scoping study is less likely to seek to address very specific research questions nor, consequently, to assess the quality of included studies (Arksey and O'Malley, 2005).

Scoping reviews can be used in a number of ways, for example identifying research gaps and summarizing findings of research (Arksey and O'Malley, 2005). They can also be used to inform systematic reviews, in particular to:

- explore the extent of the literature in a particular domain without describing findings in detail.
- help identify appropriate parameters of a review (i.e. define the targeted population, intervention, comparison, and outcomes, otherwise known as PICO).
- to identify the potential scope of a systematic review and associated costs (Brien et al., 2010, Arksey and O'Malley, 2005).

Scoping review would likely reveal that there are numerous forms of interventions used in a range of settings. This would help to identify a more specific research question of interest, based on what was already known (or not known) for each of those interventions within each setting, as well as the commissioning body and/ or review author's area of interest. It would also facilitate a more realistic budget estimate based on the breadth of the work required, since a scoping review should provide an indication of the number of studies likely to be retrieved for each of those interventions/settings. Scoping reviews to inform systematic reviews typically do not include a quality assessment of included studies, which limits data synthesis and interpretation. They are therefore intended to be conducted reasonably rapidly (Armstrong et al., 2011).

To make this method of literature review more rigorous, Arksey and O'Malley developed a framework for conducting a scoping review (Davis et al., 2009). Levac et al. (2010) developed scoping review and introduce six key phases; which are listed below.

- Identifying the research question,
- Identifying relevant studies,
- Study selection,
- Charting the data,
- Collating, summarizing and reporting the results,
- Optional consultation.

The studies analysed in this literature review are both quantitative and qualitative. These research methods complement each other: qualitative studies allow an understanding of patient and professionals opinions toward diabetes management; quantitative research allows an understanding of epidemiology and clinical effectiveness. There is much debate in the research literature about the relative merits of both qualitative and quantitative research, with some researchers proclaiming the superiority of one approach over another. It is argued that these debates are not important. What is important is that the most appropriate research methodology is used to address the research topic in question (Aveyard, 2007).

Qualitative research is concerned with exploring meaning and phenomena in their natural settings. There are a wide variety of approaches to qualitative research. Russell and Gregory (2003) reported that over 40 approaches have been identified in the literature. Aveyard, (2007, pp: 31) stated that qualitative data “are not numerical but are collected, often through interview, using the words and descriptions given by participants. The data are used to generate understanding and insight of the situation being researched. There is no use of statistics in qualitative research, the results are descriptive and interpretative".

2.1.2. Results of search

The search phase of systematic review yielded 127 citations (**Figure 2.1**). After screening titles and abstracts, 56 citations potentially met the inclusion criteria. Of these: 21 were clinic or hospital based studies, 10 were systematic reviews, 6 were general reviews, 4 were non- randomised clinical trials, 2 were unrelated to the study focus, 1 was in the Chinese language, 1 wasn't related to diabetes, 1 was an observational study, 1 concerned the economic impact of diabetes, and 1 was a narrative review. In total, 8 studies met the inclusion criteria and were included in this systematic review.

2.1.3. Demographic and contents of intervention, control and training methods of included studies

The characteristics of the included studies included were:

- 1 cluster randomised controlled trial in which the participating pharmacies were randomly assigned to either the intervention or control group (Mehuys et al., 2011);
- studies conducted in India (Venkatesan et al., 2012, Ganawar et al., 2014);
- studies in Europe (Ali et al., 2012, Mehuys et al., 2011, Kjeldsen et al., 2015);
- 1 in USA (Kraemer et al., 2012) , one in Brazil (Paulo et al., 2016) and one in Iran (Jahangard-Rafsanjani et al., 2015).

All the studies took place in community pharmacies. Pharmacist interventions varied across the included studies and encompassed one or more of the following: counselling and education on diabetes, medication, lifestyle modification, and self-monitoring; reinforcement of medication adherence or complications screening; provision of materials such as educational leaflets; medication review; identification and resolution of drug- related problems; adjustment of pharmacotherapy; and referrals to other health care professionals. Two studies mentioned motivational interviews as a technique used to deliver advice to patients (Ganawar et al., 2014, Kjeldsen et al., 2015). In most studies the control group received usual care from physician or community pharmacist. Only one study the control group not reported type of care received (Kjeldsen et al., 2015). Overall, the included studies involved 1558 participants. The duration of follow up ranged from five months to twenty four months. A detailed description of the characteristics of included studies is presented in **Table 2.1** and **2.2**.

Most studies mentioned that community pharmacists were provided with training (see **Table 2.2**) in: pharmacotherapy; diabetes management; and referrals for eye and foot care management. As well as training on pathophysiology, pharmacology and non-pharmacological management of type II diabetes (Ali et al., 2012, Jahangard-Rafsanjani et al., 2015, Mehuys et al., 2011). One study did training on drug related problems and medication review (Gngawar et al., 2014). In another study the pharmacists attended training on patient education, empowerment, documentation and billing procedures for counselling services (Kraemer et al., 2012). There is a study that trained the pharmacists on motivational interviewing and self-efficacy in relation to behaviour (Kjeldsen et al., 2015). Two studies do not describe training of pharmacists (Venkastesan et al., 2012, Paulo et al., 2016).

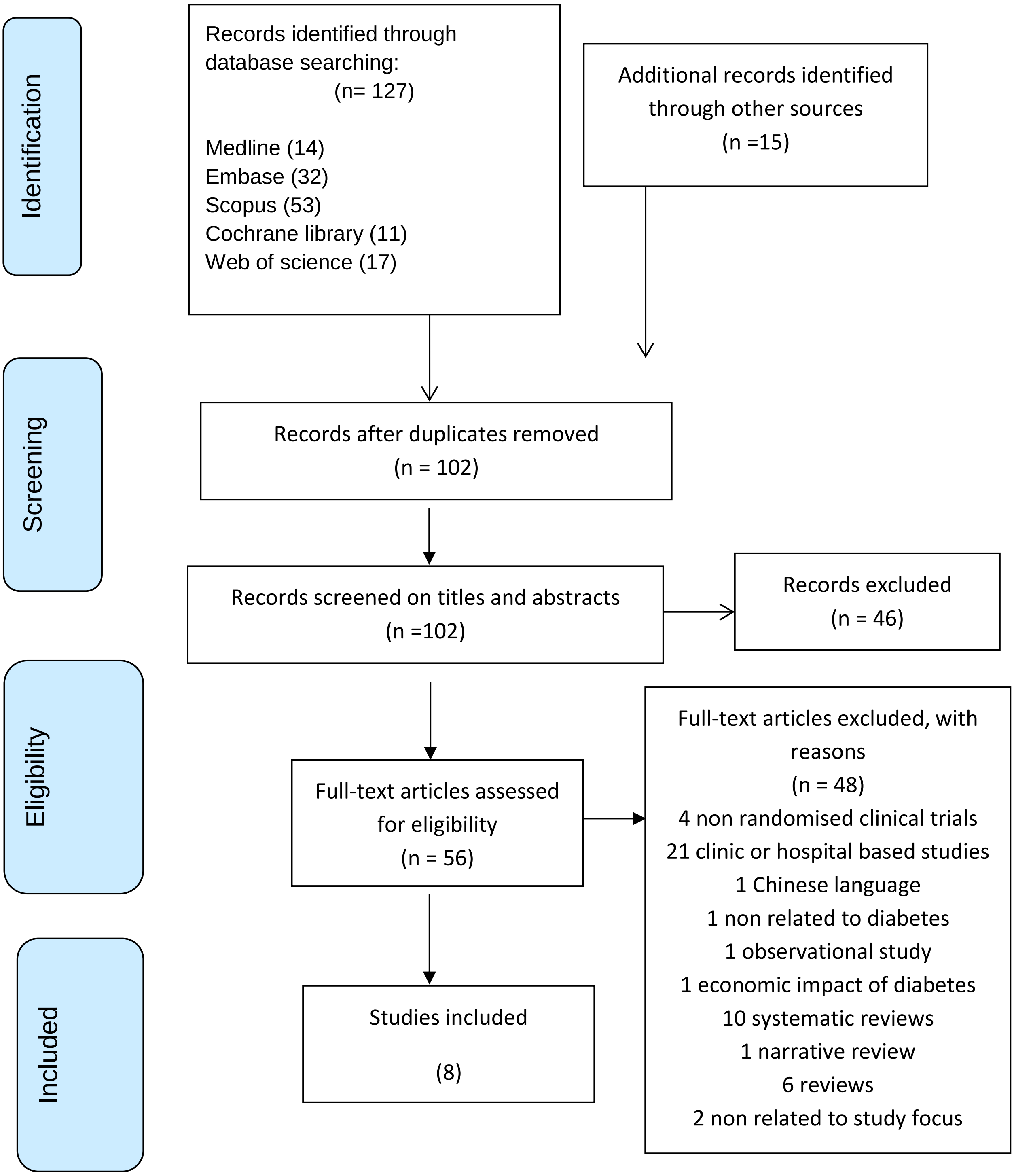


Figure 2.1: Prisma flowchart of study selection process

Table 2.1: Characteristic of included studies

Author, Year	Setting/ country	Method of study	Population (IG/CG)	Lost to follow up (IG/CG)	Age	Gender	Duration of diabetes	Duration of follow up
Ali et al., 2012	Community pharmacies/ UK	RCT	N=46 23/23	0/2	66.4 (±12.7)/66.8(±10.2)	10 (43.5%)/13 (56.5%) male	7.5 (±4.8 years)/6.8 (±3.5 years)	12 months
Jahangard-Rafsanjani et al., 2015	Community pharmacy/Iran	RCT	N=101 51/50	6/10	57.3 (±8.6)/55.9 (±8.7)	25(49%)/26(52%) female	4.6(±4.3)/5.7(±5.9) years	5 months
Venkatesan et al., 2012	Community pharmacy/India	RCT	N= 39 19/20	None of the participants lost to follow up	51.47(±9.99)/57.05(±12.05)	8 (21%)/10 (26%)male	5.21(±4.88)/5.80(±5.34)	8 months
Mehuys et al., 2011	Community pharmacy/ Belgium	Cluster RCT	N= 288 153/135	5/3	63.0/62.3 years	51.0/53.7 male	ND	24 months

Ganawar et al., 2014	Community pharmacies/ India	Prospective RCT	N= 723	ND	ND	Both groups 389 (50.80%)	Not more than 10 years: 247(34.16) 11 to 20 years: 224 (30.98) 21 to 30 years: 108 (14.94) Unknown duration: 070 (09.68)	One year
Kraemer et al., 2012	Community pharmacy/ Oregon USA	RCT	N= 67 36/31	1/1	55.6(±6.8)/52.6(±9.2)	14(38.89%)/19(61.29%) female	9.9(±10.3)/8.0(±7.4)	One year
Paulo et al., 2016	Community pharmacy/Brazil	Prospective RCT Single blinded study	N= 89 47/42	Non	56.89(±10.0)/59.62(±9.0)	27(57.5%)/22(52.4%) female	6.63(±6.63)/7.2(±6.6)	6 months

Kjeldsen et al., 2015	Community pharmacy/ Denmark	RCT	N= 205 Comparing to interventions basic intervention BI= 39/ Extended intervention EI=41/ Control group CG= 125	BI/EI/CG=6/4/23	BI/EI/CG= 63.1(±8.8)/63.4(±7.8)/62.1(±10.2)	BI/EI/CG=22(57.9%)/25(59.5%)/78(62.4%)	ND	6 months

Table 2.2: The intervention, control and training community pharmacist's components of included studies along with primary and secondary outcomes

Author/ Year	Pharmacist intervention	Control	Pharmacist training	Primary outcomes	Secondary Outcomes
Ali et al., 2012	Patients in the intervention group received a programme of education about diabetes, its treatment and associated cardiovascular risk factors. These patients were seen for monitoring / counselling by a community Pharmacist	Patients in the control group did not receive specific counselling or education over and above usual care.	The training about up to date diabetes management and referrals, an overview of the use of diagnostic equipment's and the data collection forms.	BMI, BP(mmHg) BG (mmol/l), HbA1c(mmol/l) HbA1c(%), LDL (%), HDL (%), Total cholesterol(mmol/l), Triglycerides (mmole/l)	Short Form-36 Diabetes Knowledge Test (DKT) Beliefs about Medicines Questionnaire (BMQ) Satisfaction with Information received about Medicines(SIMS) Diabetes Quality of Life (DQOL)
Jahangard-Rafsanjani et al., 2015	Qualified community pharmacist educated patients about diabetes medications, clinical goals, self-care activities and self-monitoring of blood glucose. As well recommended physician visit when necessary	Patients in this group received usual care from the physician during the study period. Baseline assessments were performed by the community pharmacist at the recruitment visit.	The training about pharmacotherapy of diabetes and health care professionals on diabetes education	HbA1c	Medication adherence Self-care activity

Venkatesan et al., 2012	Patients in the intervention group received diabetic medication counselling, printed educational material and instructions on dietary regulation, exercise and lifestyle modifications from the community pharmacist,	The control group patients did not receive a counselling	No pharmacist trained mentioned	FPG BMI	Diabetes care profile questionnaire to measures social and psychological factors Self-care practices. Diabetes knowledge test
Mehuys et al., 2011	Counselling on diabetes and complications, medication and healthy lifestyles, facilitation of medication adherence, and reminders about annual eye and foot examinations.	Patients in the control group received usual pharmacist care	the intervention pharmacists underwent a training session on the pathophysiology of type II diabetes and its nonpharmacological and pharmacological management according to t treatment guidelines, and the study protocol. The control pharmacists only received training on the study protocol	FPG HbA1c	Medicine adherence. Diabetes knowledge test Diabetes Self-management
Ganawar et al., 2014	Patients received medication review and provided with counselling of Drug Related Problems (DRPs) to identity	The control group was given usual care (no medication review given) For the control	Community pharmacist in intervention arm trained on DRPs in medication review while control pharmacists not attending medication review. However, both	Calculation of the incidences of DRPs	• FPG • Hypoglycaemic episodes, morbidity, adverse effects • total incidence of patient visit to

	complexity of medication regimen and problems detected. As well, provided with psychological Aspect Treatment (PAT) to educate patients about medicine contraindication, indications, side effects administration and frequency of the medicines.	group no PAT test was performed.	groups of community pharmacists were explained on motivational interviewing and decision making as well as communication skills.		diabetiologist for consultation of probable drug related problem • The incidence of clinic visit was obtained from the prescriptions.
Kraemer et al., 2012	Patients in the intervention group received counselling on managing diabetes from pharmacist	Control-group participants were provided written educational information about managing diabetes (no counselling)	The participating pharmacists attend training on patient education and empowerment, clinical intervention techniques, patient care documentation, and billing procedures for counselling services. As well, the pharmacists trained on the protocol of study in terms of collecting patient information, educating and coaching patients with diabetes, and documenting outcomes, they were not	HbA1c	LDL, HDL, cholesterol, Triglycerides, total to HDL ratio, fasting blood glucose, other clinical parameters; systolic and diastolic blood pressure, weight circumferences, BMI.

			required to use specific educational or clinical practice protocols. In addition, they required to fax, e-mail, or mail a progress note to the patient's primary care physician after each visit		
Paulo et al., 2016	The intervention group had monitoring program performed by community pharmacist to evaluate DRPs.	Received usual care	Not mentioned	HbA1c FPG	Triglycerides Total Cholesterol HDL cholesterol LDL cholesterol Blood Pressure
Kjeldsen et al., 2015	The intervention model sought to identify drug-related problems as well as issues experienced by the patient in relation to medicines use, and consequently find individually tailored solutions to address the identified problems. Despite the potential complexity of the problems, the targeted solutions could be simple, e.g. provision of medication	Not mentioned	The pharmacist trained on delivering aspects of intervention model. Control and intervention pharmacists trained on motivational interviewing adapted from Levensky et al., 2007. Pharmacists in EI provided with additional training tools for coaching to support establishing and maintaining self-efficacy in relation to behaviour change	Systolic blood pressure (mm Hg)	Medication adherence

	information or introducing a dose administration aid (DAA).				

2.1.4. Studies risk of bias

The risk of bias varied among the included 8 studies (see **Chart 2.1**). In half (50.0%) of the studies, the allocation sequence was adequately generated, and random number tables or a computer-generated randomized list were the most commonly used methods. The allocation sequence was concealed in only one study (13%).. Only one study (13%) blinded participants and personnel to pharmacist intervention. None of the studies described clearly that the outcome assessment was executed by an assessor blinded to treatment assignment. Only three studies (38%) reported outcome data completely, and 6 studies (75%) were free from other sources of bias. The details of Cochrane bias judgement is provided in **Appendix 6**.

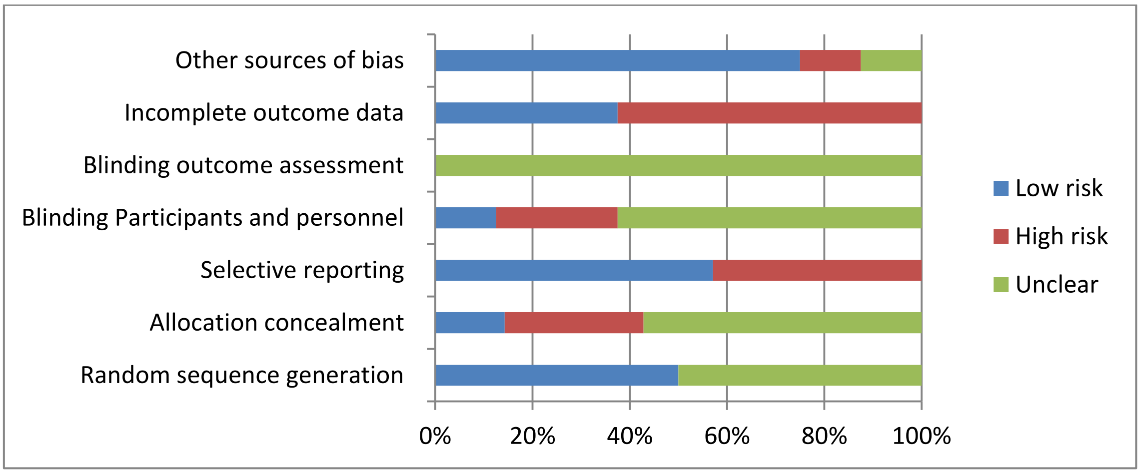


Chart 2.1: Risk of bias in included studies presented as percentage across all studies

2.1.5. HbA1c and FPG outcomes in included studies

Five studies considered the primary outcome measures HbA1c and FPG (Ali et al., 2012, Jahangard-Rafsanjani et al., 2015, Venkatesan et al., 2012, Mehuys et al., 2011, Kraemer et al., 2012, Paulo et al., 2016). HbA1c mean value decreased in the intervention group during the follow-up period in five of the studies (Ali et al., 2012, Jahangard-Rafsanjani et al., 2015, Venkatesan et al., 2012, Mehuys et al., 2011, Kraemer et al., 2012, Paulo et al., 2016). In three studies, the reduction in HbA1c in the intervention group was greater than that recorded in the control group by approximately 0.5% or more (Ali et al., 2012, Jahangard-Rafsanjani et al., 2015, Mehuys et al., 2011). In another study, HbA1c mean value decreased in the intervention group by 0.12%, while there was a 0.41% increase in the control group (Paulo et al., 2016). Five studies presented balance between the baseline HbA1c mean values of both groups (Ali et al., 2012, Jahangard-Rafsanjani et al., 2015, Venkatesan et al., 2012, Mehuys et al., 2011, Kraemer et al., 2012, Paulo et al., 2016). Only one study show the statistical significance of improvement (p-value <0.001) in HbA1c (Ali et al., 2012). The other studies showed no significant improvement between groups in HbA1c (Jahangard-Rafsanjani et al., 2015, Mehuys et al., 2011, Kraemer et al., 2012, Paulo et al., 2016). The difference in HbA1c change from baseline to final follow up ranged from -0.34% to 1%. The detailed difference between baseline and final follow up is explained in **Chart 2.2**

Regarding FPG, 4 studies reported this parameter as an outcome measure (**Table 2.4**). There was always a decrease in FPG in the intervention group from baseline to final follow-up, and all 4 studies reported a greater improvement in this outcome in the intervention group than the control group. The difference in change between groups ranged from -7.2 mg dL-1 to -25.74 mg /dL. This was not statistically significant with one exception (Ali et al., 2012). The changes between baseline line and final follow up in FPG among the four studies are described in **Chart 2.2**

2.1.5.1. *Blood pressure, lipid profile and body mass index outcomes*

Five studies out of eight evaluated the change in systolic and diastolic blood pressure during the course of study (Ali et al., 2012, Jahangard-Rafsanjani et al., 2015, Kraemer et al., 2012, Paulo et al., 2016, Kjeldsen et al., 2015) (see Table 2.4). One study reported the change in systolic blood pressure during the study (Kjeldsen et al., 2015). Only one study shows that the reduction in mean systolic blood pressure in intervention group from baseline to final follow-up better improvement than control group (Ali et al., 2012). Only one study shows that the systolic blood pressure increased in the intervention group compared with control group (Jahangard-Rafsanjani et al., 2015). For systolic blood pressure the difference in change between the groups ranged from -5.3mmHg to 0 3mmHg and was shown to be statistically significant only in two studies (Alie et al., 2012, Kjeldsen et al., 2015).

Four studies reported diastolic blood pressure outcome (Ali et al., 2012, Jahangard-Rafsanjani et al., 2015, Kraemer et al., 2012, Paulo et al., 2016) (see **Table 2.4**). Two studies show that diastolic blood pressure increased in the intervention group compared with control group (Jahangard-Rafsanjani et al., 2015, Kraemer et al., 2012). The mean diastolic blood pressure decreased in intervention group only in two studies (Ali et al., 2012, Paulo et al., 2016). The difference in change between both groups ranged from -1.8 mmHg to 1.8 mmHg.

Three studies out of eight reported lipid profile, one study reported lipid profile as a primary outcome (Ali et al.,2012) and the other two studies reported it as a secondary outcome (Kraemer et al., 2012, Paulo et al., 2016). The normal value for Total Cholesterol was less than 200mg/dL and the normal range for LDL Cholesterol was 100-129mg/dL. For HDL Cholesterol the range was 40—59 mg/dL and higher values are considered better protection against heart disease, for Triglycerides the normal value was less than 150 mg/dL.

Total cholesterol reduced in the intervention group more than control group in two studies (Kraemer et al., 2012 and Paulo et al., 2016). The difference in change between both groups ranged from -6.7 mg/dl to 0.49mg/dl and one study shows this to be statistically significant (Ali et al., 2012) (see **Table 2.5**).

Regarding LDL cholesterol, three studies reported data on this outcome. The mean reduction in intervention group was more than control group (see **Table 2.5**). However, the difference in change in both groups ranged from -4.1 to 1.43mg/dl, which means two studies show an increase in LDL level (Paulo et al., 2016 and Ali et al., 2012).

Among the three studies reporting HDL cholesterol as an outcome measure (see **Table 2.5**), two studies described gradual increase in the intervention group from baseline to follow up. One study observed a decrease in intervention group (Kramer et al., 2012). Nevertheless the difference in change between both groups ranged from -2.7 to +0.37mg/dl.

Triglycerides (TG) was reported on in three studies (**Table 2.5**). Two studies show there is decrease in TG in intervention group compared with control group (Kraemer et al., 2012, Paulo et al., 2016). However, the difference in change between both groups was not statistically significant in three studies (see **Table 2.5**) (Ali et al., 2012, Kraemer et al., 2012, Paulo et al., 2016).

For studies reporting Body Mass Index (BMI), two reported the baseline data for both groups but not the final follow up (see **Table 2.6**) (Venkatesan et al., 2012, Mehuys et al., 2011). The other two studies show reduction in intervention group compared with control group. The difference in change in two groups ranged between -0.5 kg/m^2 and -1.02kg/m^2.

Table 2.3: The results for HbA1c in included studies

HbA1c (%)								
Author	IG Before	IG After	Mean Change	CG Before	CG After	Mean Change	Difference in change between groups	p-value [a]
Ali et al., 2012	8.2	6.6	-1.6	8.1	7.5	-0.6	-1	$p<0.001$ [a]
Jahangard-Rafsanjani et al., 2015	7.6	6.6	-1	7.5	7	-0.5	-0.5	$p=0.09$ [a]
Venkatesan et al., 2012	NDR	NDR	NDR	NDR	NDR	NDR	NDR	NDR
Mehuys et al., 2011	7.7	7.1	-0.6	7.3	7.2	-0.1	-0.5	$p=0.009$ [a]
Ganawar et al., 2014	NDR	NDR	NDR	NDR	NDR	NDR	NDR	NDR
Kraemer et al., 2012	7.28	6.78	-0.5	7.38	7.22	-0.16	-0.34	$p=0.0757$ [a]
Paulo et al., 2016	7.1	6.98	-0.12	7.2	7.61	0.41	-0.53	$p= 0.143$ [a]
Kjeldsen et al., 2015	NDR	NDR	NDR	NDR	NDR	NDR	NDR	NDR

[a] P-value Independent Sample t-test (to show intervention effect between intervention and control group)
b Convert mmol/l to mg/dl by multiple 18

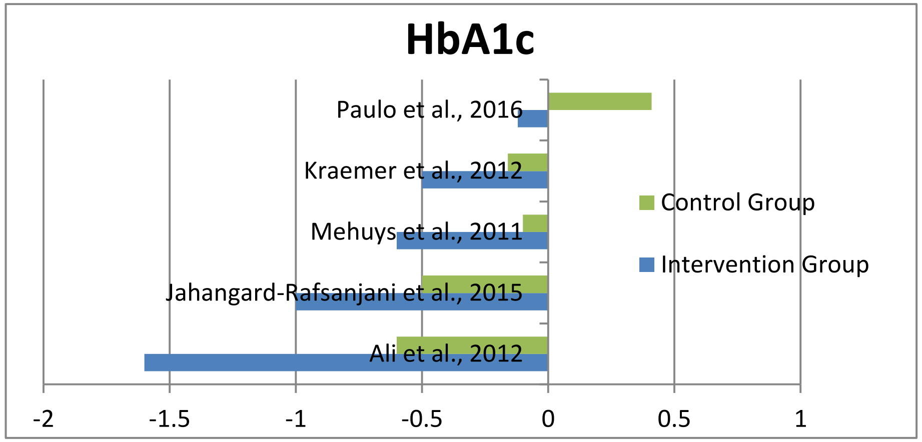
NDR No Data Reported

IG Intervention Group

CG Control Group

Table 2.4: The results for Fasting Plasma Glucose (FPG) in included studies

FPG (mg/dl)								
Author	IG Before	IG After	Mean Change	CG Before	CG After	Mean Change	Difference in change between Groups	P-value[a]
Ali et al., 2012	158.4[b]	123.84[b]	-34.56	171.54[b]	162.72[b]	-8.82	-25.74	p<0.001[a]
Jahangard-Rafsanjani et al., 2015	NDR	NDR	NDR	NDR	NDR	NDR	NDR	NDR
Venkatesan et al., 2012	155.58	NDR	NDR	150.3	NDR	NDR	NDR	NDR
Mehuys et al., 2011	154.1	138.8	-15.3	153.9	145.8	-8.1	-7.2	p=0.193[a]
Ganawar et al., 2014	NDR	NDR	NDR	NDR	NDR	NDR	NDR	NDR
Kraemer et al., 2012	148.8	128.1	-20.7	137.2	126.8	-10.4	-10.3	p=0.8552[a]
Paulo et al., 2016	159.3	147.64	-11.66	157.7	159.8	2.1	-13.76	p=0.125[a]
Kjeldsen et al., 2015	NDR	NDR	NDR	NDR	NDR	NDR	NDR	NDR



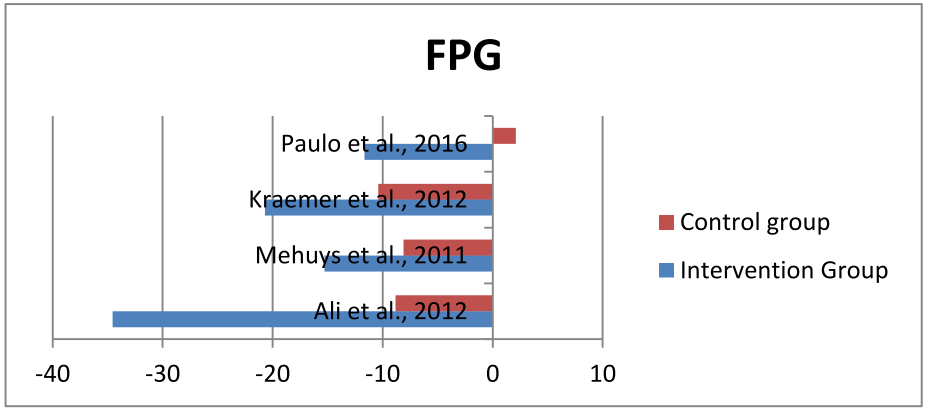


Chart 2.2: The changes from baseline and final follow-up in both parameters HbA1c and FPG

Table 2.5: The results of Blood pressure among included studies

Blood Pressure (mmHg)									
Author		IG B	IG F	Mean Change	CG B	CG F	Mean Change	Difference in change between Groups	P-value[a]
Ali et al., 2012	systolic BP	146.26	126.17	-20.09	136.22	139.17	2.95	-23.04	P=0.012[a]
	Diastolic	87.13	81.04	-6.09	85.65	81.7	-3.95	-2.14	P=0.748[a]
Jahangard-Rafsanjani et al., 2015	systolic BP	132	132.8	0.8	136.4	134.2	-2.2	3	P=0.5[a]
	Diastolic	81.7	82.2	0.5	83.3	82	-1.3	1.8	P=0.5[a]
Venkatesan et al., 2012	systolic BP	NDR	NDR	NDR	NDR	NDR	NDR	NDR	NDR
	Diastolic	NDR	NDR	NDR	NDR	NDR	NDR	NDR	NDR
Mehuys et al., 2011	systolic BP	NDR	NDR	NDR	NDR	NDR	NDR	NDR	NDR
	Diastolic	NDR	NDR	NDR	NDR	NDR	NDR	NDR	NDR
Ganawar et al., 2014	systolic BP	NDR	NDR	NDR	NDR	NDR	NDR	NDR	NDR
	Diastolic	NDR	NDR	NDR	NDR	NDR	NDR	NDR	NDR
Kraemer et al., 2012	systolic BP	136.3	132.7	-3.6	129.5	131.8	2.3	-5.9	P=0.9644[a]
	Diastolic	78.4	80.6	2.2	75.3	79.3	4	-1.8	P=0.6144[a]
Paulo et al., 2016	systolic BP	137.7	137.28	-0.42	137	136.74	-0.26	-0.16	P=0.625[a]
	Diastolic	83	82.56	-0.44	82	81.51	-0.49	0.05	P=0.820[a]
Kjeldsen et al., 2015	systolic BP	138	131.3	-6.7	139	137.6	-1.4	-5.3	P=0.033[a]
	Diastolic	NDR	NDR	NDR	NDR	NDR	NDR	NDR	NDR

Table 2.6: The results of Lipid Profile among included studies

Lipid profile									
Author	Lipid	IG B	IG F	Mean Change	CG B	CG F	Mean Change	Difference in change between Groups	P-value[b]
Ali eta., 2012	TC	4.15mmol/l[a] 160.4 mg/dl	4.12mmol/l[a] 159.3mg/dl	-0.03	3.66 mmol/l[a] 141.5mg/dl	3.14 mmol/l[a] 121.4mg/dl	-0.52	0.49	P<0.001
	TG	1.35mmol/l[a] 119.5 mg/dl	1.52mmol/l[a] 134.6 mg/dl	0.17	1.44 mmol/l[a] 127.5 mg/dl	1.78 mmol/l[a] 157.6mg/dl	0.34	-0.17	P=0.404
	LDL	2.35 mmol/l[a] 90.8 mg/dl	1.97mmol/l[a] 76.1mg/dl	-0.38	1.81mmol/l[a] 69.9 mg/dl	1.25mmol/l[a] 48.3mg/dl	-0.56	0.18	P<0.001
	HDL	1.19mmol/l[a] 46.0 mg/dl	1.46mmol/l[a] 56.4 mg/dl	0.27	1.2mmol/l[a] 46.4 mg/dl	1.25mmol/l[a] 48.3mg/dl	0.05	0.22	P=0.041
Jahangard-Rafsanjani et al., 2015	TC	NDR	NDR	NDR	NDR	NDR	NDR	NDR	NDR
	TG	NDR	NDR	NDR	NDR	NDR	NDR	NDR	NDR

[a] Convert mmol/l to mg/dl in TC (Total Cholesterol, HDL, and LDL multiply mmol/L by 38.67, For triglycerides multiply mmol/L by 88.57.

b P-value Independent Sample t-test

	LDL	NDR	NDR	NDR	NDR	NDR	NDR	NDR	NDR
	HDL	NDR	NDR	NDR	NDR	NDR	NDR	NDR	NDR
Venkatesan et al., 2012	TC	NDR	NDR	NDR	NDR	NDR	NDR	NDR	NDR
	TG	NDR	NDR	NDR	NDR	NDR	NDR	NDR	NDR
	LDL	NDR	NDR	NDR	NDR	NDR	NDR	NDR	NDR
	HDL	NDR	NDR	NDR	NDR	NDR	NDR	NDR	NDR
Mehuys et al., 2011	TC	NDR	NDR	NDR	NDR	NDR	NDR	NDR	NDR
	TG	NDR	NDR	NDR	NDR	NDR	NDR	NDR	NDR
	LDL	NDR	NDR	NDR	NDR	NDR	NDR	NDR	NDR
	HDL	NDR	NDR	NDR	NDR	NDR	NDR	NDR	NDR
Ganawar et al., 2014	TC	NDR	NDR	NDR	NDR	NDR	NDR	NDR	NDR
	TG	NDR	NDR	NDR	NDR	NDR	NDR	NDR	NDR
	LDL	NDR	NDR	NDR	NDR	NDR	NDR	NDR	NDR
	HDL	NDR	NDR	NDR	NDR	NDR	NDR	NDR	NDR

Kraemer et al., 2012	TC	177.1	165.4	-11.7	186.4	181.4	-5	-6.7	P=0.1362
	TG	164.6	155.8	-8.8	172.2	166.4	-5.8	-3	P=0.9231
	LDL	99.5	95.6	-3.9	100.7	100.9	0.2	-4.1	P=0.4411
	HDL	46.2	39.9	-6.3	50.7	47.1	-3.6	-2.7	P=0.1594
Paulo et al., 2016	TC	191.1	181.53	-9.57	209.9	210.3	0.4	-9.97	P=0.187
	TG	186.7	177.87	-8.83	176.1	185.8	9.7	-18.53	P=0.314
	LDL	110.8	102.6	-8.2	131	130.2	-0.8	1.43	P=0.254
	HDL	43	43.63	0.63	43.6	43.86	0.26	0.37	p=0.479
Kjeldsen et al., 2015	TC	NDR	NDR	NDR	NDR	NDR	NDR	NDR	NDR
	TG	NDR	NDR	NDR	NDR	NDR	NDR	NDR	NDR
	LDL	NDR	NDR	NDR	NDR	NDR	NDR	NDR	NDR
	HDL	NDR	NDR	NDR	NDR	NDR	NDR	NDR	NDR

Table 2.7: Body Mass index among included studies

BMI (Kg/m2)								
Author	IG B	IG F	Mean Change	CG B	CG F	Mean Change	Difference in change between Groups	P-value
Ali et al., 2012	30.84	26.98	-3.86	29.82	28.73	-1.09	-2.77	NDR
Jahangard-Rafsanjani et al., 2015	29.3	29.1	-0.2	29.4	29.7	0.3	-0.5	P=0.02
Venkatesan et al., 2012	25.09	NDR	NDR	25.81	NDR	NDR	NDR	NDR
Mehuys et al., 2011	31	NDR	NDR	30.5	NDR	NDR	NDR	NDR
Ganawar et al., 2014	NDR	NDR	NDR	NDR	NDR	NDR	NDR	NDR
Kraemer et al., 2012	NDR	NDR	NDR	NDR	NDR	NDR	NDR	NDR
Paulo et al., 2016	NDR	NDR	NDR	NDR	NDR	NDR	NDR	NDR
Kjeldsen et al., 2015	NDR	NDR	NDR	NDR	NDR	NDR	NDR	NDR

2.2. How to improve type II diabetes management?

Once diagnosed, type II diabetes patients are initially managed by a combination of restricted energy intake and an increase in physical activity (Keenan, 2010). From this perspective the study focused on two aspects of diabetes management: self-management (i.e. how people manage everyday life in terms of diet, exercise, feet care, eye care) and medicine management (i.e. oral hypoglycaemic adherence). In the long term, diabetes cannot be managed by medicine or diet alone, as it is on first diagnosis. Older people have to take oral hypoglycaemic tablets to control blood glucose levels, and may progress to management with insulin.

The current study focuses on the improvement of type II diabetes management. So, the starting point for review was searching through clinical diabetes guidelines, specifically I started by creating a comparison between SIGN diabetes guidelines and LDCG. Generally speaking, the reason for comparison was to identify any differences or any missing information in the LDCG and fill any gaps in diabetes knowledge by using SIGN, which was a more comprehensive standard (see **Table 2.3**). Another reason for using SIGN rather than NICE guidelines was that SIGN provided recommendations based on current evidence of best practice in the management of diabetes. The grade of a recommendation relates to the strength of the evidence on which it is based. It does not reflect the clinical importance of the recommendation and also SIGN was broader than NICE. The information in both guidelines was similar but SIGN determined strength of recommendation according to clinically based evidence. The main aim of comparison was to emphasise those aspects of diabetes care that should be followed and implemented by health care providers to improve diabetes care and glycaemic control. It was also an aim to make sure that there was no difference in the standard of care that was recommended to enable design of the intervention study for improvement in glycaemic control.

Table 2.8: The key difference between Scottish Intercollegiate Guideline Network and Libyan Diabetes Care Guideline

Source: (SIGN, 2013, NDCGAB, 2010)

Key differences	**Scottish Intercollegiate Guideline Network SIGN**	**Libyan Diabetes Care Guideline LDCG**
Clinical recommendation	Ranked by using four grades A,B,C,D	No rank for recommendation to enable health professional to work on
Based on evidence	The rank of recommendation based on the strength of supporting evidence	The evidence not mentioned
Management of diabetes	Divided according to types, classification, risk factors and complication of diabetes	Divided according to diabetes control such as glycaemic control and treatment option.
Lifestyle management	Focused on four areas: • delivery of lifestyle interventions, • structured education, • self-monitoring of glycaemic control. • specific areas of smoking, obesity, physical activity, healthy eating and alcohol. (more comprehensive)	The focus of lifestyle management on two aspects is diet and exercise. (less comprehensive)
Delivery of lifestyle intervention	• Intervention based on theoretical knowledge model. • Using computer assisted education package and telephone prompting. • Training healthcare professionals	Not mentioned
Structured education	More precise description which provides structured education to both type I and II diabetes for adults, children and adolescents	Highlighted in a general way and focused more on the structure of programme and what it should include.

Structured education for type II	Focused on on principles of adult learning (including patient empowerment and experiential learning) is associated with improved psychological well-being, reduced anxiety and overall improvement in quality of life in patients with type II diabetes	Not mentioned
Physical activity	Highly recommended that people with type II diabetes should be encouraged to participate in physical activity or structured exercise to improve glycaemic control and cardiovascular risk factor	Highlights the importance in general.
Performance and duration of exercise	• aged 18–64 years should build up to achieve a minimum of 2.5 hours each week of moderate- intensity • vigorous-intensity aerobic physical activity intensity75mis each week o	• 150min/week of moderate –intensity. • 90min/week of vigorous aerobic exercise
Days recommended of exercise	30 mins of activity on at least five days of the week.	At least 3 days/week

Self- monitoring of blood glucose (SMBG) in people with type II diabetes	May be considered in the following groups of people with type II diabetes who are not using insulin: • Those at increased risk of hypoglycemia • Those experiencing acute illness • Those undergoing significant changes in pharmacotherapy or fasting, for example, during Ramadan • Those with unstable or poor glycaemic control (HbA1c>8.0% (64 mmol/mol)) • Those who are pregnant or planning pregnancy. • Self-monitoring of urine glucose in people with type II diabetes is not recommended	• People with type II diabetes on insulin should be taught how to self-monitor and record their blood glucose levels with home meters and to adjust their insulin doses accordingly • For people not on insulin, SMBG may be useful in achieving glycaemic goals, through support for self-management • People should receive initial instruction, but also routine follow-up evaluation of SMBG techniques and their ability to use data to adjust therapy
Smoking cessation	Healthcare professionals should continue to monitor smoking status in all patient groups. (Similar recommendation)	Smoking cessation counselling and treatment should be offered to smokers.
Weight management	Strongly recommend that obese adults with type II diabetes should be offered individualised interventions to encourage weight loss (including lifestyle, pharmacological or surgical interventions) in order to improve metabolic control.	It is not mentioned
Healthy eating	People with type II diabetes can be given dietary choices include: 1. simple caloric restriction 2. reducing fat intake 3. Consumption of carbohydrates with low rather than high glycaemic index.	The total food energy and carbohydrate intake should be distributed as follows: • Carbohydrates>50% (encouraging complex unrefined high fibre carbohydrate and moderate sucrose intake)

	4. restricting the total amount of dietary carbohydrate (a minimum of 50 g per day appears safe for up to six months)	• Fats 30-35% (<10% saturated fat, <10% polyunsaturated fat & >10% monounsaturated fat, with low trans-fatty acids). • Proteins 10–15% (decreasing with age) • Five portion of fruit and vegetable per day
Pharmacological management of glycaemic control in people with type II diabetes	The pharmacological management of glycaemic in SIGN more detailed and the strategy of taking Oral Hypoglycaemic medicines (OHMs) more comprehensive. The recommendations sets in Appendix (6)	The pharmacological management of OHMs similar to SIGN guideline but lack of detailed strategy and the recommendations not included the strategy of therapy (see appendix 7)

2.2.1. Type II diabetes self-management

Patients with chronic conditions make day-to-day decisions about self-managing their illnesses. This reality introduces a new chronic disease paradigm: the patient-professional partnership, involving collaborative care and self-management education. Diabetes self-management education is defined as a collaborative process through which persons living with diabetes gain knowledge and skills to modify behaviour and eventually manage themselves successfully (American Diabetes Association, 2014). Self-management education complements traditional patient education in supporting patients to live the best possible quality of life with their chronic condition. Whereas traditional patient education offers information and technical skills, self-management education teaches problem-solving skills. A central concept in self-management is self-efficacy, that is, confidence to carry out behaviour necessary to reach a desired goal. Self-efficacy is enhanced when patients succeed in solving patient identified problems (Bodenheimer et al., 2002).

Self-care is defined as "*a deliberate action that individuals, family members and the community should engage in to maintain good health. Ability to perform self-care varies according to many social determinants and health conditions*" (WHO, 2009: 1). Self-care regimens include diet modification, adherence to medication, regular exercises, foot care and self-monitoring of blood glucose (Funnell et al., 2007). The deterioration of glycaemic control after completing intensive management may 'relapse' because of return to old behaviours (Rothman & Elasy, 2005). Patients may know what should be done and be motivated to change by the management program, but they may relapse back to their ‘unhealthy’ behaviours if they encounter problems or barriers to achieving self-care activities.

For people with type II diabetes, the impact of trying to make multiple lifestyle changes to control their conditions can be substantial, and is one of the major barriers to people initiating change. Some people feel they have been told to make so many changes in their lives that they cannot manage all of them, so feel it is pointless or hopeless and do not do anything. It is important to remember that it is not how much the ‘objective’ impact that diabetes has on people, but what each person perceives the impact to be. Some people say that diabetes has changed their life, but they see the changes in lifestyle in a positive way, such as making them feel healthier. As a result they do not perceive the impact of lifestyle changes to be so great (Banks, 2005).

There has been much research on how people’s belief about the long-term complications of diabetes relate to how they manage their condition. Many health care professionals have worked on the basis that the more severe people think the complications are, and the more likely they think they are to get these complications, the more proactive individuals will be in managing their diabetes. However, this does not always seem to be the case. Although some research shows that a greater perceived threat of complications (more serious, or more likely to get them) is associated with better self-management, there are as many studies that that show no relationship, and even some that show the greater perceived threat is associated with poorer self-management (Skinner et al., 2005).

In self-management, a person’s trust in self-efficacy plays a key role in implementing the behaviours required to achieve the desired outcomes

(Bodenheimer et al., 2002). In guiding the relationship between health professionals and patients, empowerment has been recognized as an alternative to compliance since; through this approach, patients take responsibility for their own choices and for the respective consequences (Funnel & Anderson, 2003; Anderson et al., 2005). Several studies have linked self-management education to a better understanding of diabetes and improved self-care behaviours to reduced levels of HbA1c, weight loss and a better quality of life (Norris et al., 2001; Norris et al., 2002; Gary et al., 2003; Ellis et al., 2004; Warsi et al., 2004; Heinrich et al.,2010; Steed et al., 2003). Self-management education guides and helps these patients to take decisions, resolve problems, learn self-care behaviours and set up an active collaboration with the team of health professionals. This leads to improved clinical outcomes, health status and quality of life, optimal cost–benefit ratios, with an approach focused on empowerment and patient- and family-centred care (Norris et al., 2002; Funnell & Anderson, 2003; Lewin et al., 2005; Chen & Li, 2009; Funnell et al., 2007).

One factor not always considered in research studies is how people feel about whether or not they can affect their chances of getting complications. If people feel they are highly likely to get complications, and they feel it is inevitable no matter what they do to manage their diabetes, then it might make sense to them not to follow the diet, activity, monitoring and medication recommendations. After all, what is the point of doing it all if it will not change things? Trying to scare people into following treatment recommendations is often counter-productive. A more positive approach is to help people to understand their diabetes and the possible complications. By encouraging people to think about the options available for preventing these problems, the health care team can help people reflect more accurately on their risks. In many cases this alone can have a substantial impact on people's quality of life (Banks, 2005).

Patients, through support and education about self-management, assume charge of the management of their own disease and are encouraged to resolve their own problems in partnership with health professionals (Holman and Lorig, 2000). Patients and health professionals jointly decide about the care to be provided (collaborative care). Patients show a higher level of adherence to recommendations, thus achieving better outcomes (van Dam et al., 2005; Williams et al., 2007; Peyrot & Rubin, 2006; Tang et al., 2010; Duncan et al., 2011). Internal motivations of the patient are more effective for lifestyle change than external motivation (Arnold et al., 1995; Glasgow & Anderson, 1999; Anderson & Funnell, 1999).

Self-management and self-management support (SMS) are central concepts in diabetes care (Funnell et al., 2012, Haas et al., 2012). This can be credited to recognition of the burden of diabetes (Nicolucci et al., 2013), to the role of health behaviours in clinical outcomes (Ford et al., 2009, Li et al., 2008), and to the Expanded Chronic Care Model (Coleman et al., 2009, Stellefson et al., 2013). Despite widespread acceptance, a useful question to ask is how well self-management support is being translated into clinical care. Barr et al., (2003) stated that self-management support interventions might result in too much focus being placed on individual responsibility, creating a judgmental environment in which patients are blamed for their circumstances. This judgmental context can stem from a fundamental misunderstanding of self-management support. Unless the context in which self-management interventions are implemented reflects self-management support, potentially valuable behavioural-change interventions might be found to be wanting and to be abandoned (Vallis, 2015).

US studies of diabetes self-management in Hispanics have reported low income, low education, low acculturation, spoken language and literacy issues, different cultural beliefs and values, such as fatalism and machismo, limited social support and medical comorbidities as barriers to effective self-management (Ghaddar et al., 2010, Weiler and Crist, 2009). It has been reported by Elkharam et al (2013) that diabetes knowledge in the Libyan population is very poor for both types of diabetes, especially among those classed as non- educated. Modernization of Arab countries and the rapid development in large cities and towns increased urbanization of the population; an important difference between urban and rural sectors. In the Arabic-speaking countries there is an increased exposure to a more Western lifestyle (Madanat et al., 2008). In Saudi Arabia, 25.5% of the urban population is diabetic in comparison with 19.5% in rural areas. There are also regional differences in the prevalence of type II diabetes, with the Northern (27.9%) and Eastern (26.4%) provinces experiencing greater rates than the Southern region (18.2%), where a rural lifestyle is more common and the population less prone to obesity than those on the Northern and Eastern provinces (Al-Nozha et al., 2004; Al Othaimeen et al., 2007). The ratio of people with type II diabetes in urban and rural areas is 235 to 100 in Oman and 400 to 100 in Egypt (Al-Lawati, et al., 2002; Herman, 1997). In the US, more Hispanics live in poverty (23.2%) than non-Hispanic Whites (8.6%) (DeNavas-Walt et al., 2011) and many more Hispanic Americans with diabetes (60%) than non-Hispanic Whites with diabetes (28%) have an annual income below $20,000 (Gary et al., 2003). Hispanics with diabetes also have poorer access to care and poorer health status (Nwasuruba et al., 2009). Lack of health insurance (Lopez-Class and Jurkowski, 2010) and the cost of medications have been identified as barriers to diabetes self-management for Mexican-Americans (Benavides-Vaello et al., 2004, Bailey et al., 2012). Major contributory factors for type II diabetes mellitus, which is most prevalent in Middle Eastern countries, include low activity levels, poor diet, and excess body weight (Yahia, 2014). Lack of health awareness, health beliefs, attitudes, and lifestyle are all contributing to the rising prevalence of obesity and diabetes in the Middle East (Musaiger, 2004). In particular, lack of awareness about nutritional information and the significance of healthy eating have led to adoption of a poor diet (Al-Kaabi et al., 2008, Abahussain and El-Zubier, 2005). Social and economic changes are also important. These include changing lifestyles in terms of urbanization and changing dietary habits. Increased wealth resulting from oil production leads to most people able to own cars as a consequence there is decreased physical activity along with rising levels of obesity and smoking (Azab, 2001, WHO, 2008).

Another potential barrier is resistance to change on the part of healthcare professionals, many of whom have been traditionally trained to deliver care to their patients; different skills are needed to effectively support people living with long-term conditions such as diabetes. Although healthcare professionals may see value in helping people to self-manage, it can cause conflict between people with diabetes who want to do things for themselves and healthcare professionals who feel they are responsible for these things, or in some cases do not agree with them. Part of the process of supporting self-management involves healthcare professionals increasing their own skills and confidence in understanding what self-management means, so they can learn to support people with diabetes more effectively (Diabetes UK, 2009)

Barrier identification is critical in minimizing adverse effects on adherence to self-management programmes (Sprague et al. 1999). Self-management programmes are complex, require time and involve all aspects of a person's life. Patient adherence is not only affected by barriers, but also by people's lifestyle and confidence in their ability to implement a self-management plan (Whittemore et al. 2005). Each day patients make multiple decisions about managing their diabetes based on their knowledge, beliefs, attitudes, resources and support systems. Healthcare providers who are sensitive to the barriers experienced by patients and the effective strategies they use can work collaboratively to facilitate the development of realistic self-management programmes. Underestimating or not identifying barriers to self-management adversely affects adherence (Aljasem et al. 2001).

Suboptimal adherence, once viewed as a patient problem, is now seen as an indication of patients' self-management of chronic disease within the interactive framework of providers, healthcare systems, families and communities (Walker and Usher, 2003). Within this framework, the dynamic interaction of patient, healthcare providers and systemic factors can influence the overall management of diabetes (Brown et al., 2002). The care of patients with diabetes has largely encompassed new and more efficacious diabetic treatments and improved medication delivery systems (American Diabetes Association, 2003), but literature highlights the importance of integrating self-management education (Brown et al., 2002; Norris et al., 2002; Po, 2000). To adequately address barriers to diabetes self-management and identify strategies to overcome them, it is important to examine whether there are additional barriers that still exist (Onwudiwe et al., 2011).

2.2.1.1. Diabetes Self-care behaviour

Evidence from earlier studies supports the notion that having good knowledge and education influences good care and can reduce diabetes complications significantly (Al-Qazaz et al., 2011). Knowledge not only enhances the self-care behaviours (Aschner et al., 2012), but it enables DM patients to adhere to their treatment effectively. It has also been noted that age, lack of resources and perceived side effects have significant association with poor adherence to medication (Wabe et al., 2011).

Knowledge, self-care behaviours and adherence to medications in diabetes could be helpful for early case detection, prevention, and minimization of complications, and improvements of the quality of life of affected individuals. Previous studies have reported poor health outcomes to be associated within insufficient knowledge, poor self-care behaviours and adherence to medications among diabetic patients (Islam et al., 2015, Feleke et al., 2013, Al-Maskari et al., 2011).

Recent work on the social determinants of health found that diabetes outcomes are influenced by factors such as level of education, economic conditions, and social support with specific factors being found to have a direct relationship with diabetes self-care behaviours (Walker et al., 2014a, Walker et al., 2014b). As such, the need for tailored interventions and treatment plans that target individual, social, and behavioural factors associated with diabetes care are being given greater attention (Schulz et al., 2005, Ludwig et al., 2011). However, better understanding of the underlying mechanisms that increase risk of poor diabetes outcomes, outside of traditional demographic factors, may lend to greater methods of prevention and development of treatment interventions (Campbell et al., 2017).

Self-care behaviours are an integral aspect of comprehensive care for patients with type II diabetes, including exercise, diet, blood sugar testing, foot care, and adherence to oral medications (American Diabetes Association, 2014, Centers for Disease Control and Prevention, 2011). As diabetes self-management education (DSME) is a critical element for improving self-care, clinicians and researchers continue to investigate how to enhance current efforts. (American Diabetes Association, 2014, Funnel et al., 2012, Marrero et al., 2013). Current standards note that there is no one 'best' approach, and recommend consideration of behavioural and psychosocial strategies and development of personal strategies (Funnel et al., 2012, Delamater et al., 2001, Ismail-Beigi et al., 2011). One overarching framework to use in considering how to develop individualized strategies is consideration of how social determinants of health may influence whether patients engage in self-care behaviours. Social determinants of health are the circumstances in which people are born, live, work, and age (Department of Health and Human Services, 2014). This includes socioeconomic circumstances, neighbourhood environments, psychosocial factors, and upstream political, economic and sociocultural drivers (Marmot, 2010). Current evidence suggests that social determinants of health influence diabetes prevalence and outcomes (Marmot, 2010, Walker et al., 2014). Consideration of social determinants known to influence DSME may assist in understanding how to personalize DSME efforts and improve self-care (Walker et al., 2015).

2.2.2. Lifestyle intervention toward type II diabetes

Combined lifestyle interventions (CLIs) in primary care, including dietary advice and physical activity, have been advocated as an effective instrument in efforts to reduce the growing problem of overweight and obesity (Tuomilehto et al., 2001; Brown et al., 2009). Enhanced levels of physical activity and a healthier diet maintained over a longer period of time have shown to be associated with better health outcomes for obese individuals (Brown et al., 2009; Ho et al., 2012). However, low enrolment rates, high dropout rates and incomplete implementation have limited the effectiveness of CLIs in real life situations (Reinehr et al., 2009; Linmans et al., 2011). In contrast to reaching immediate, short-term changes (Wang et al., 2008, Unick et al., 2011), it has proved difficult to achieve sustained behaviour change, which is required to prevent weight regain and chronic diseases such as type II diabetes or cardiovascular diseases among obese individuals (Wing et al., 1998; Wu et al., 2009).

Research has demonstrated that the probability of maintaining higher levels of physical activity and healthier dietary behaviour improve when people are more intrinsically motivated to change their behaviour (Silva et al., 2011; Teixeira et al., 2012). In a recent review on motivation and self-regulation in relation to weight reduction (Teixeir et al., 2012), the authors indicated that interventions may so far have focused too much on influencing cognitions and skills, but ignored the importance of perceived autonomy in the process of adopting new behaviours (Teixeir et al., 2012).

Intrinsic motivation is the most pronounced type of autonomous motivation described in Self-Determination Theory (SDT) (Deci & Ryan, 1990; Ryan & Deci, 2000). This theory distinguishes 3 types of motivation: amotivation, extrinsic motivation and intrinsic motivation. Extrinsic motivation is sub-divided into four types of motivational regulation: two controlled types, external and introjected regulation; and two autonomous types, identified and integrated regulation. The theory indicates that the quality of the motivation to engage in certain behaviour can shift from motivation and/or more controlled types of motivational regulation towards the autonomous types of regulation and towards the ultimate form of autonomous motivation, intrinsic motivation. To reach this shift, SDT indicates that there are three basic needs (autonomy, competence and relatedness) that should be supported. If individuals experience an insufficient level of one of these needs it hampers the shift towards autonomous motivation.

To promote the shift in motivation towards the more autonomous types, facilitator-led CLIs have been developed. An example is the Dutch BeweegKuur (exercise therapy) intervention, which, in addition to physical activity support and dietary advice, includes lifestyle coaching by means of motivational interviewing (Helmink et al., 2010; Berendsen et al., 2011). Through the combination of these three components the intervention touches on the need for autonomy by means of lifestyle coaching, on competence by means of lifestyle coaching and physical activity and dietary behaviour guidance and on relatedness by means of group sessions. By the inclusion of autonomy supportive lifestyle coaching (LSC), the intervention intends to produce sustainable changes in energy balance related behaviours. The objective of the intervention is to enhance overweight or obese participants' levels of physical activity and improve their dietary behaviour. The BeweegKuur intervention distinguishes 3 programmes that all include 7 lifestyle coaching sessions and 2 individual and 5 group sessions with a dietician. The programmes differ in the extent and intensity of physical activity support. The independent exercise programme includes no physical activity support by a physical therapist (PT).

While the Start-up programme includes six PT sessions in three to four months and the supervised exercise programme includes 3–4 months of intensive PT-guided training at least twice a week. Individuals are assigned to the programmes on the basis of their weight-related health risk, which is based on their Body Mass Index BMI, their waist circumference and the presence of risk factors for type II diabetes or cardiovascular disease, or of comorbidities. A low or moderate level of physical activity is also an inclusion criterion for the BeweegKuur intervention. The LSC carries out the primary assessment and includes people in the intervention. LSCs involved in the BeweegKuur intervention, which in most cases are general practitioner assistants and sometimes physical therapists, are trained in motivational interviewing (MI), a method for autonomy-supportive coaching (Rutten et al., 2014).

2.3. Pharmacy practice in developing countries

As pharmacists from around the world communicate, in developed and developing countries, they find that there are many practice similarities, areas of focus include:

- Assuring effective delivery of medications to patients

- Assisting health care providers and patients to become more knowledgeable about medications
- Promoting medication adherence
- Assuring the quality of medicines
- Assuring access to medications under conditions of inadequate financial resources

The culture and traditions in different countries can determine the place of pharmacists in society and the reliance that health care consumers place on pharmacists, who are the most accessible health care professional and have great opportunity to recommend and implement wellness and treatment strategies. What pharmacists can contribute to health care is determined by the nature of their training and the legal authority within their country. However, in many countries the number of pharmacists not sufficient to provide the type of care that is needed. Knowing how care by pharmacists is provided in different countries will assist all pharmacists in identifying the best practices and striving to use them in their own country. While pharmacy practice varies considerably among countries, there is a consistent and growing interest in progressive pharmacy practice that goes by different terms, such as clinical pharmacy or pharmaceutical care. It is patient-focused practice where the pharmacist has a responsibility to the patient (Fatherlrahman, et al., 2016).

An important factor that will surely advance practice in all countries is the quality of pharmacy education, both for students entering the profession and for practitioners advancing their knowledge. Pharmacy education is becoming more standardized at a higher level than in the past. As education improves, so will practice progress in pharmacy education and practice is coming from many different countries throughout the world. All countries have something to learn from what others are doing to improve practice (Fatherlrahman, et al., 2016).

The pharmaceutical sector and its overall conditions in developing countries are under researched. There is a scarcity of studies and information on pharmaceutical health services systems (Fatherlrahman, et al., 2016). In many parts of the world, pharmacists have played a significant role in the provision of pharmaceutical care services. The dilemma of pharmacy education and practice in developing countries are that pharmacy colleges in developing countries strives to produce a qualified pharmacy graduate prepared with essential knowledge, skills, competencies, and the positive attitude required for practice. As a result students are overloaded with heavy subjects, such as analytical and organic chemistry, pharmacognosy, pharmaceutics, and other courses taught by didactic or practical methods (Fatherlrahman, et al., 2016). However, pharmacy graduates in many developing countries are the only graduates among other professions who do not actually apply what they have been taught in colleges. The International Pharmaceutical Federation (IPF), in its policy document on good pharmacy education practice, recommended that basic first degree education programmes should provide pharmacy students and graduates with a sound and balanced grounding in the natural pharmaceutical and health care services that provide the essential foundation for pharmacy practice in a multi-professional health care delivery environment. According to Waterfield (2010) it is important for the colleges to have a comprehensive curriculum on pharmaceutical sciences and practice-related courses and for educators to prepare the future knowledge-based pharmacists.

Waterfield (2010: 3) stated that "*the use of tacit skill and knowledge by pharmacists is well documented through terms such as reflective practice*" when coming to practice pharmacy graduates discover that very small proportions of that overwhelming knowledge and skills that they have been given are actually needed for practice as pharmacists. On the other hand, in many developing countries and in many situations pharmacists jobs are occupied by non-pharmacists such as traditional practitioners, drug sellers, pharmacy assistants in community pharmacy, veterinary doctors, and non-health related individuals in the field of marketing and promotion of pharmaceutical products, and chemists and chemical engineers in the pharmaceutical industry (both as production managers and as quality control analysis) (Fatherlrahman, et al., 2016). The author stated that they are not holding a discrimination philosophy against those professions. However, there is a great concern for the possibility of a substantial mismatch between the practice of pharmacists and the pharmacy education provided to them. Basically, if pharmacy education and practice matched each other properly, for example the right knowledge and skills provided to practice, there would be no room for others to complete with pharmacists. Those competitors practice in a manner similar to how pharmacists are supposed to practice and with qualifications unrelated to those normally received by pharmacy graduates.

2.3.1. Information regarding pharmacy and medicine schools in Libya

The purpose of highlighting some higher education infrastructure in Libya is to provide the reader with the picture of the quality of education given to health care workers in Libya. There are two universities, Garyounis (now called Benghazi University) in Benghazi and El Fateh (now called Tripoli University) in

Tripoli. The first medical students graduated from Garyounis in January, 1977, and from El Fateh in January, 1980. Most of the medical students are Libyan; the number of women admitted to the medical school has risen steadily to almost one-third of the total students. The training the medical students received was at first almost entirely from foreign academics. The language of medical instruction is English. It was natural therefore, that many of the lecturers themselves should have received their training under a British-based system (Lancet, 1982).

All medical care and services are free. Almost all private practice has been abolished (Lancet, 1982). The health service is administered jointly by committees of the Ministry of Health and the faculties of medicine of the universities. Policy decisions are determined by committees on which all groups of workers within the health service are represented. The hospitals and health centres were initially staffed by doctors from abroad. They are drawn mainly from India, Pakistan, Egypt, and Eastern Europe. Gradually, however, Libyan graduates are taking over from these foreign doctors.

At that time the universities extended to postgraduate teaching and persist till now. They have in some departments made formal arrangements with institutions abroad, such as the Liverpool School of Tropical Medicine, in specified areas of training for doctors, senior technicians, and nurses. At present Libya sends many Libyan doctors abroad on scholarships to train as specialists. In 1982 the Libyan population was only 3 million (Lancet, 1982).

The first college of pharmacy was established in Tripoli University (previously El Fateh) in 1975, offering a bachelor’s degree in pharmacy as well as a master’s degree in pharmaceutical sciences (Lancet, 1982). Admission to pharmacy faculty is based upon secondary school performance; there is a pre-requisite of a one year course followed by four years in pharmacy school. However, there are no Pharm D programmes. Opportunities for graduates to work are similar to other countries where the vast majority of pharmacists work in the private sector, typically as community pharmacists, whereas institutional and pharmaceutical industry positions are very limited. While community pharmacies are readily accessible to the public, the poor image of pharmacists in this country prevents them from being fully utilized in health care facilities. Until very recently, graduates did not have to pass any qualification exam to get the practice license or to complete their registration within the Libyan Society of Pharmaceutical Sciences. However, this is no longer true as pharmacy leaders and stakeholders have already started to establish their new reforms agenda (Abduelkarem, 2014).

2.3.2. Pharmaceutical services

With a strategic location in the heart of the community, extended opening hours and no appointment required for seeking healthcare advice, community pharmacy has great potential as a setting in public health. Moreover, pharmacy in the region has often become patients' first point of healthcare contact (Chalker et al. 2005, Ngorsuraches et al. 2008, Chua et al. 2013). These benefits provide a platform for more proactive involvement of community

Pharmaceutical services are expanding in some parts of developing countries. As elsewhere, community pharmacy practice in South-East Asia has evolved in response to the changing healthcare environment. Significantly, provision of a range of healthcare services beyond traditional dispensing has been trialled in community pharmacies across the region. Although relatively new, such services include blood pressure monitoring, chronic disease screening, smoking cessation and weight management programmes (Nimpitakpong et al. 2010, Dhippayom et al. 2013, Chua et al. 2013, Phimarn et al. 2013). However, there is a dearth of evidence on the extent of implementation of these services in everyday practice and their impact on public health

The impact of pharmaceutical services on patient outcomes has been reviewed by Singhal et al. (1999). They searched MEDLINE (1966–December 1998) and International Pharmaceutical Abstracts (1970–December 1998). They found 21 out of 95 selected studies met their criteria to: be in community pharmacy and ambulatory care settings; have randomized, controlled designs; with major tasks performed by pharmacists; and measuring economic, clinical, and humanistic outcomes (ECHO). Few studies employed adequate research designs to control threats to internal and external validity. No study measured all three types of economic, clinical and humanistic outcomes (ECHO). They recommended that in order to obtain a comprehensive and accurate picture of the impact of pharmaceutical services on patient outcomes, an attempt must be made to measure all three (ECHO) variables while employing adequate research design.

The Ashville project was designed to assess short-term clinical, economic, and humanistic outcomes of pharmaceutical care services (PCS) for patients with diabetes in community pharmacies. A clear temporal relationship was found between PCS and improved $HbA1_C$, improved patient satisfaction with pharmacy services, and decreased all-diagnosis costs. Findings from Ashville project demonstrates that pharmacists provided effective cognitive services and disprove the idea that pharmacists must be certified diabetes educators to help patients with diabetes to improve clinical outcomes (Cranor and Christensen, 2003).

2.3.3. The accessibility of community pharmacist

Community pharmacists are the most accessible health care professional (Centres for Disease Control and Prevention, 2012, Food and Drug Administration, 2011). According to Gamble (2011) pharmacists are among one of the most trusted groups of professionals in the United States. According to Simone (2013) "*Nearly all Americans live within five miles of a community pharmacy. As the face of neighbourhood healthcare, pharmacists are better serving patients through accessible, convenient and personalized health care in partnership with other healthcare providers.*"

In the UK, there are 438 million visits to community pharmacy a year for health related reasons. There are over 11,500 community pharmacies in England providing NHS services. Community pharmacies are highly accessible, located in the heart of communities where people live; work and shop in the areas of highest deprivation almost 100% of households live within walking distance of a pharmacy. 96% of the population can get to a pharmacy within 20 minutes by walking or using public transport. Adults in England visit a pharmacy on average 16 times a year. Many pharmacies are open for extended hours in the evenings and weekends and nearly 900 of them are open for 100 hours a week. Pharmacists train for five years, are experts in medicines and can be consulted without an appointment (NHS, 2015). In New Zealand there are 0.22 pharmacies per 1000 people, while in European countries numbers per 1000 people vary from around 0.05 in Denmark to 0.78 in Greece (Kanavos et al., 2011). In countries with areas of low population density (e.g., New Zealand, Australia, Norway, Finland and Canada) access to pharmacies in rural and remote areas can be problematic (Law et al., 2011; Norris, 1997; Sunderland et al., 2006).

2.3.4. Pharmaceutical Care

Pharmaceutical care (PC) in developing countries is still a work in progress because the healthcare and educations systems work differently, for instance in Jordan the undergraduate pharmacy education (BSc) has little focus on pharmaceutical care skills and therapeutics. This contributes to the situation where the principal responsibilities of the pharmacist in Jordan are dispensing and marketing (Al-Wazaify and Albsoul-Younes, 2005).

In Qatar, around 800 pharmacists are working in different pharmacy practice settings including hospitals, community pharmacies and clinics. Around 55% are male pharmacists, and more than 70% obtained their highest pharmacy degree from one of four countries: Egypt, Jordan, India, and Sudan (El Hajj et al., 2011, Supreme Council of Health, 2013). El Hajj et al. (2014) stated that pharmaceutical care in Qatar does still not exist. However, Qatar pharmacy students had positive attitudes toward PC. But they mentioned there are barriers to practicing it such as lack of access to patient information, inadequate drug information sources, and time constraints. If there is no pharmaceutical care how can pharmacists have a positive attitude towards it? It may be that students know about the components of pharmaceutical care from their educational modules but not practice in the real world.

Several studies have discussed the practice of community pharmacy in the UAE and have shown that most community pharmacists only counsel patients. However, UAE has taken initiatives to allow and prepare community pharmacists to practice ‘extended’ roles (Sadek et al., 2015).

While in Libya students study four-years plus one year foundation and the programme consists of mixed education: theoretical and laboratory work, three sessions of 8-10 week summer training in the fields of community pharmacy, hospital pharmacy, clinical pharmacy, and pharmaceutical technology conducted at the end of the first, second, and third years of the four-year program (Abrika et al., 2012). No study reveals that the concepts of pharmaceutical care are taught at undergraduate level unless there are some initiatives to introduce social pharmacy in the programme of undergraduate studies in Libya (Abrika et al., 2012). I remember when I was studying an undergraduate pharmacy practice module we got some educational materials that focused on what patient centred care means. Patient-centred care, defined as respecting and responding to the needs and preferences of patients, empowering them to make decisions that best fit their individual needs, has been identified by the Institute of Medicine as an essential element of high-quality care (Institute of Medicine Committee on Quality of Health Care, 2001). Patient-centred care is a quality of personal, professional, and organizational relationships. Thus, efforts to promote patient-centred care should consider patient-centeredness of patients (and their families), clinicians, and health systems (Epstein and Street, 2007, Epstein et al., 2010). Helping patients to be more active in consultations changes centuries of physician-dominated dialogues to those that engage patients as active participants (Epstein and Street, 2011).

2.3.5. The Impact of pharmacist on diabetes care

Most studies confirmed that pharmacists can improve glycaemic control for type II diabetes patients compared with usual care (Aguiar et al., 2016, Collins et al., 2011, Hassali et al., 2015, Omran et al., 2012, Pousinho et al., 2016, Sapkota et al., 2015). Pharmacists have expanded their services further than drug dispensing, and they often participate directly in the management of patients with the delivery of clinical services (Campbell, 2002). Pharmacists are especially alert to certain aspects of care, such as the occurrence of adverse drug reactions and interactions, and specific features associated with aging and comorbidities (Pousinho et al., 2016). Because of the complex nature of diabetes, and as recommended by the American Diabetes Association, a collaborative and integrated team approach should be sought for its management, in which the patient must play an active role along with a multidisciplinary health care team (American Diabetes Association, 2015). In this context, pharmacists can also contribute positively to diabetes management by providing pharmaceutical care programs, which involve working closely with the patient and other health care professionals in designing, implementing, and monitoring therapeutic plans to achieve specific outcomes that will improve patient quality of life (Hepler and Strand, 1990).

The studies were principally conducted in outpatient clinics where pharmacists commonly worked collaboratively with the medical staff and discussed face-to-face on drug therapy problems (Aguiar et al., 2016). According to Van et al. (2012), the level of trust and cooperation of the physicians seems to be higher in this setting compared with a community pharmacy, where contacts are usually not personal and occur at a distance. Despite the trend towards greater reduction in HbA1c levels in a non-community pharmacy setting, trials vary widely in relation to pharmacist health interventions and population characteristics, generating results based on substantial statistical heterogeneity (Aguiar et al., 2016). Among the key components of pharmacist interventions, the level of pharmacist-patient interaction presented great variability across studies. This finding may reflect the need to develop clinical pharmacy services adapted to the context reality, but also the uncertainty about which of the options could be more effective. Although increasing evidence indicates that telephone interventions are effective for glycaemic control in patients with diabetes (Liang et al., 2011). However, meta-analysis found no difference in effect compared with studies that performed face-to face contact only (Aguiar et al., 2016). Furthermore, the duration of pharmacist intervention was not associated with change in HbA1c levels, contrary to a recent systematic review on patient activation interventions that showed the greatest improvements in HbA1c levels with longer study duration (Bolen et al., 2014).

There has been a growing body of literature assessing the effectiveness of pharmacist involvement in the management of type II diabetes in various settings. The number of systematic reviews has been published on this topic, and some of them evaluated pharmacist interventions in patients with type II diabetes relatively small (Aguiar et al., 2016, Antoine et al., 2014, Collins et al., 2011, Omran et al., 2012, Pimouguet et al., 2011, Pousinho et al., 2016). One narrative review assessed seven evidence based factors from diabetes guideline: glycaemic, cholesterol and blood pressure control; medication, lifestyle, education, and cardiovascular risk factors. The findings concluded that even though pharmacists' contribution towards improving clinical outcomes of diabetes patients was well documented; the methods used to deliver structured, consistent evidence-based care were not clearly stipulated. Therefore, approaches to achieving long term continuity of care are uncertain.

2.4. Patient diabetes health literacy

This thesis focuses on type II diabetes knowledge, attitudes and self-care behaviour. Therefore, this section is essential to review the diabetes heath literacy among type II patients with diabetes. Literacy has been defined as "*an individual's ability to read, write, speak, and compute and solve problems at levels of proficiency necessary to function on the job and in society, to achieve one's goals, and develop one's knowledge and potential*" (Ad Hoc Committee on Health Literacy for the Council on Scientific and American Medical Association, 1999: 552). Health literacy is defined as "a constellation of skills, including ability to perform basic reading and numerical tasks required to function in the health care environment (Ad Hoc Committee on Health Literacy for the Council on Scientific, Affairs American Medical, Association, 1999: 553)

Patients with low literacy may have trouble in reading prescriptions, following medical instructions, and interacting with the health care system. They also have lower disease specific knowledge, report lower quality of life, and have poorer health related outcomes – even after adjusting for potential confounders such as educational level, insurance, and other factors (Ad Hoc Committee on Health Literacy for the Council on Scientific Affairs and American Medical Association, 1999, Rothman et al., 2003). Numeracy, as an important component of literacy, can be defined as the ability to understand and use numbers in daily life (Rothman et al., 2006). Numeracy is particularly important to patients with diabetes because diabetes requires self-management skills that rely on mathematics such as counting carbohydrates, interpreting glucose monitoring, applying a sliding scale for insulin, and calculating insulin doses based on carbohydrate intake. These skills require not only basic maths skills, but also the ability to apply those maths skills in the context of diabetes care (Xu et al., 2014).

Low literacy is common among patients with diabetes, and appears closely associated with less knowledge of diabetes self-management and worse clinical outcomes (Rothman et al., 2004, Rothman et al., 2003, Schillinger et al., 2002, Williams et al., 1998). Williams et al. (1998) found that 55% of diabetes patients in the United States had inadequate literacy. It was reported that, of patients with inadequate literacy, 50% did not know the symptoms of hypoglycaemia, 62% did not know how to treat hypoglycaemia, and 42% did not know the normal blood glucose range despite the fact that 73% of the patients had attended previous diabetes education. Among over 400 patients with diabetes, Schillinger et al. (2002) observed an independent association of poor literacy with worse glycaemic control and higher rates of retinopathy. Most of the studies, to date; on the role of literacy in health care have focused specifically on verbal literacy with little examination of quantitative skills (Xu et al., 2014).

While there is a strong correlation between verbal literacy and quantitative skills, there are many patients who have adequate verbal literacy but are still unable to use math skills appropriately or are anxious/ intimidated about math (Cavanaugh et al., 2008). Recent studies have demonstrated that providing low literacy materials or low literacy forms of communication can improve patient comprehension for patients with both low and high literacy (Dewalt et al., 2004, Pignone et al., 2005). A randomized controlled trial (RCT) of a comprehensive disease management intervention demonstrated that literacy was a significant factor in predicting patients' improvement in HbA1c from the intervention, and suggested that addressing literacy could improve patient outcomes (Rothman et al., 2004). Two coordinated RCTs performed at two academic medical centres of the United States from 2006 to 2008 rigorously examined the role of addressing both literacy and numeracy, and found that the literacy and numeracy-sensitive diabetes care can lead to significant improvements in glycaemic control, self-efficacy, and other outcomes (Cavanaugh et al., 2009).

A survey conducted in older diabetes patients in Beijing showed that diabetes knowledge was very limited in this population (Hu et al., 2013). In a study conducted in Hong Kong, a negative correlation was observed between literacy and glycaemic control among patients with diabetes (Tang et al., 2008) Addressing literacy and numeracy through improved healthcare provider communication skills and improved educational materials is a potentially successful strategy. It is an innovative approach to optimize patient understanding, promote shared decision-making, and enhance patient self-efficacy and self-management behaviours (Xu et al., 2014).

Proper diabetes self-care requires patients to have considerable knowledge, a range of skills, and to sustain multiple health behaviours (Funnell et al., 2009, Bodenheimer et al., 2002). Not surprisingly, limited literacy has been linked to inadequate treatment knowledge, poorer self-care and glycaemic control (Wolf et al., 2005, Sarkar et al., 2010). Interventions that have been designed for use among individuals with lower literacy skills are needed; some approaches have been developed and evaluated, with promising results (Rothman et al., 2004, Kandula et al., 2009). Yet, questions remain on how best to implement these interventions in the most effective, efficient, and sustainable manner. This is critical for patients receiving primary care in community health centres that have limited resources and disproportionately care for patients with limited literacy (Paasche-Orlow et al., 2005).

A national team, led by the American College of Physicians Foundation, developed a patient-centred, low literacy intervention promoting diabetes self-care (Seligman et al., 2007, DeWalt et al., 2009). It includes:

- Diabetes Guide that uses plain language and descriptive photographs to teach core diabetes concepts and empower patients to initiate behaviour change;
- Brief counselling strategy to assist patients in developing short term, explicit and attainable goals for behaviour change (‘action plans’);
- Training module for healthcare providers (physicians, nurses, medical assistants) that using the Diabetes Guide as a teaching tool; and
- Electronic tracking and monitoring tools for primary care practices.

A prior efficacy trial found that the Diabetes Guide improved patient knowledge, self-efficacy, intent to adopt recommended behaviours, and reduced diabetes related distress (Wallace et al., 2009, DeWalt et al., 2009).

A study conducted by Wolf et al. (2014) in Missouri in US to compare two implementation approaches for a health literacy diabetes intervention designed for community health centres. One of approaches called a ‘carve-in’ strategy composed of medical directors, physicians, nurses, and medical assistants at clinics assigned to receive an extensive orientation to the Diabetes Guide. Other approach titled ‘carve-out’ strategy consists of clinic staff briefly oriented to the purpose of the trial. They were asked to distribute the Diabetes Guide to eligible patients, briefly review it and then refer them to a diabetes educator who would contact them by telephone. Both approaches had tracking systems to follow up patients via telephone at 2 weeks and 2 months, and via telephone or in-person at 3, 6, and 9 months. The difference was that ‘carve in’ counselling of patients was provided by clinic staff and ‘carve out’ counselling was provided by a diabetes educator. The study found that the carve-out model was a more reliable approach for contacting patients over time to initiate action plans compared to the carve-in arm. This was backed by patients’ own recall of activities, and their greater satisfaction with and desire to continue to receive services in the carve-out arm. The study seems to show that a diabetes educator engaged with patients in delivering counselling more than clinic staff.

Although health literacy is a complex and multifaceted construct, researchers have developed instruments that assess literacy skills using health-context materials. Two such literacy assessments are widely used. One is the Test of Functional Health Literacy in Adults (TOFHLA), (Lopez-Class and Jurkowski, 2010, Baker et al., 1999) which is the instrument most often used for literacy assessment in health care research. The TOFHLA is available in English and Spanish and has good psychometric characteristics, but the length of time required for administration of the TOFHLA (18 to 22 minutes for the full version and 7 to10 minutes for a short version) precludes its use in busy primary care settings. The second test, the Rapid Estimate of Adult Literacy in Medicine

(REALM), can be administered quickly (less than 3 minutes) but it, too, has limitations. In particular, the REALM is only available in English (Gottfredson, 1997, Baker et al., 1999). The Newest Vital Sign (NVS) is the most recent instrument developed to measure health literacy (Weiss et al., 2005). The Newest Vital Sign (NVS) is a 6-item literacy assessment structured around the activity of reading and demonstrating an understanding of information included on a nutrition label. The NVS is brief and available in both English and Spanish. Information on the validity of the NVS is limited to a single study that compared the NVS against the full-length TOFHLA (Osborn et al., 2007). The NVS uses the nutrition label from an ice cream container to answer six questions which focus on participants' mathematical abilities (Weiss et al., 2005). The NVS is a functional health literacy test that is used to measure participants' comprehension of health information and whether or not they can perform the tasks they have been given (Moore, 2012). It also assesses participants' document and quantitative literacy (Morrison et al., 2014).

Physical activity, improved diet and weight loss all lead to improvements in these risk factors. Engaging people with type II diabetes in active self-management of their condition is challenging (Norris et al., 2002). Previous failure to control weight is an important factor for some in the development of the condition. Taking regular medication is also a challenge that presents difficulties. Many people with diabetes need to take nine or ten tablets a day, often on two or three occasions. Concerns about harms arising from educational materials may cause problems for some; others encounter difficulty in remembering to take their medication (Horne et al., 1999). Further developing interventions to support patients in dealing with these challenges and engage better with self-management and self-care may lead to more effective care.

Leventhal's Common Sense Model (CSM) (Leventhal et al., 1997) has been used extensively to study these self-management behaviours in people with diabetes (Hampson, 1997). It has also informed the design of numerous self-management interventions for people with diabetes (Mc Sharry et al., 2011). The CSM proposes that how people cope with their illness crucially depends upon their beliefs about the illness, specifically their beliefs about its cause, identity (symptoms and the label attached to those symptoms), timeline, consequences, and how the illness can be controlled and cured. The CSM has now been used in hundreds of published studies, usually to examine the impact of illness beliefs on coping procedures (Cameron and Moss-Morris, 2004). A major category of coping procedures consists of lifestyle behaviours such as smoking, physical activity and diet (Hagger and Orbell, 2003).

However, despite its extensive use, the extent of prediction of lifestyle behaviour by beliefs about illness is typically small. The most systematic evidence comes from a meta-analysis which examined the capacity of the CSM to predict a variety of coping outcomes, including a behavioural category: “problem focussed coping specific” (Hagger and Orbell, 2003). One possible way to improve prediction and change of these lifestyle behaviours is not only to consider beliefs about illness, as proposed by Common Sense Model (Leventhal et al., 1997), but also to consider beliefs about the behaviours being examined. The logic of targeting beliefs about behaviour rather than beliefs about illness in behaviour change interventions has already been proposed and widely accepted for the behaviour of medication adherence (Hornel, 2003).

French et al. (2013) assessed the generality of the finding that perceptions of treatment may be more predictive than illness perceptions. They demonstrated that beliefs about behaviour are at least as important as beliefs about illness in predicting several health-related behaviours. This suggests the possibility that behaviour change interventions with patient groups would be more effective by targeting beliefs about behaviour, rather than beliefs about illness.

Many factors including knowledge, psychosocial support, health beliefs or attitudes, self-efficacy, socioeconomic status and behavioural or lifestyle factors affect glycaemic control (Brown et al., 2000; Heisler et al., 2003). Diabetes knowledge is a predisposing factor that contributes to outcome expectancies related to glycaemic control (Brown 1990, Padgett et al. 1988).

However, self-efficacy seems to be a powerful predictor of glycaemic control. According to Bandura (1997), self-efficacy is a specific and dynamic behaviour, in that it focuses on beliefs about personal abilities in a specific setting or with regard to a particular behaviour, such as dieting or exercise. Enhancing self-efficacy in people with diabetes has been shown to have a positive effect on behavioural change and positively influence long-term glycaemic control (Aijasem et al., 2001; Grembowski et al., 1993; Lorig et al., 2005; Montague, 2002; Uitewaal et al., 2005). Hurley and Shea (1992) also stated that self-efficacy was the predictor of self-care, and patients with the highest self-efficacy scores reported greater adherence to diabetes treatment recommendations.

Enhancing self-efficacy may enhance diabetes self-management and improve glycaemic control. Several meta-analyses have shown the efficacy of behavioural strategies derived from social learning theory to impact self –

reported behaviours and glycaemic control (Brown 1988, 1990; Lorig et al. 2001a, b; Padgett et al. 1988). Educational strategies focused on improving an individual's attitudes and motivations, rather than just increasing knowledge, have been effective in improving diabetic control (Lockington et al. 1989). Success of a medical regimen depends on an individual's attitude towards the illness, including willingness to work with the physician to manage the diabetes and self-efficacy or confidence in his/her ability to contribute to the management of illness (Wigal et al. 1993).

2.4.1. Knowledge, awareness and practice of Type II patients with diabetes

Knowledge, attitudes and practice (KAP) can be defined as key elements to improve glycaemic control among patients with diabetes. Therefore, various studies have been conducted to assess patients' and health care provider knowledge and practice toward diabetes. In order to improve patients' outcomes and to provide health carers with required training. The knowledge, attitudes and practice (KAP) can be assessed for different topics concerning diabetes for instance some studies have assessed KAP around nutritional and eating habits. Wang et al. (2014) assessed the KAP around nutrition and eating habits for type II diabetes considering that diet is the key element in controlling blood glucose. The study was based on educational intervention for 54 patients selected randomly from 162 participants recruited from three hospitals located in Yakeshi city in China. The findings stated that the participants had positive attitudes, but relatively poor nutrition knowledge and practices. Nutritional and eating education was effective in improving diabetics' nutrition knowledge and practices, and this optimal practice helped them control blood glucose effectively. The education intervention was based on four steps:

- Nutrition lectures were given, during which food exchange lists and nutrition knowledge materials were distributed to every participant and food and nutrition hygiene knowledge was explained using real food and food models. Lectures were controlled to within 1 hour and 10–15 minutes were left for answering questions and for discussion.
- According to the knowledge misunderstandings that occurred in the questionnaire, wrong answers were explained and the relevant nutrition knowledge was given to the patients face-to-face.
- Patients and their families were taught to develop individualized nutrition therapies based on their height, weight, labour intensity, blood glucose, blood lipids, renal function, liver function and personal eating habits according to the concept of food exchange portion.
- Follow-up telephone calls were made once per month to understand patients' exercise, drugs and treatment situation and to solve their actual nutrition issues.

In the study by Breen et al (2015), the level of nutrition knowledge was lower than awareness relating to other aspects of type II diabetes, such as development and management of diabetes complications. This is not surprising, given that previous studies have suggested that dietary adherence is among the most difficult cornerstones of diabetes management (Rahati et al., 2014). Information on nutritional components has grown extensively in the past decades, and it is challenging to translate the complex messages resulting from nutritional investigations into practical guidance to patients. This may lead to the general confusion about specific components, such as the lack of information on diverse types of fats found by the authors (Breen et al., 2015). Moreover, reduction of the chronic over nutrition is extremely challenging because it is linked to central reward mechanisms (Nolan et al., 2011), which favours patients' denial or undervaluation of dietary information (Dominguez, 2015).

Some studies attribute poor knowledge of diabetes to the level of education. Al-Adsani et al. (2009) investigated the level of diabetes knowledge among 5114 patients with type II diabetes by using the Arabic Translated Michigan Diabetes Knowledge Test. The authors found that the level of knowledge was poor among participants. The KAP toward type II diabetes studied in Qatar found poor practice of: regularly inspecting feet to detect signs of neuropathy, taking medication in relation to meals, modifying doses when necessary and setting goals for therapy (Kheir et al., 2011). In Pakistan, a study was conducted to assess the general characteristics, knowledge, attitude and practices of patients with type II diabetes attending the Out-Patient Department (OPD) of Baqai Institute of Diabetology and Endocrinology (Karachi, Pakistan). Fifty-seven percent of the patients were overweight or obese. Only 10.7% had good glycaemic control. Sixty seven percent did not do exercise of any kind. The overall awareness about the risk of complications was satisfactory but the misconceptions regarding diet, insulin and diabetes were quite common. The study highlighted the need for better health information to the patient through large scale awareness programmes (Badruddin et al., 2002).

2.4.2. Knowledge, attitudes and practice toward type II diabetes among community pharmacists

Knowledge regarding diabetes pathophysiology has quickly accumulated and has led to the development of new medications. In addition to knowledge updates, the attitudes of health care professionals toward current concepts about diabetes care are even more critical. The core philosophy of modern diabetes care puts emphasis on patient autonomy and optimal utilisation of health care professionals' different specialties (Chen et al., 2004).

The proper control of the illness is dependent on the patient's adherence to medications, life style modifications, frequent monitoring of blood glucose, etc. and can be influenced by appropriate education and counselling of the patient. Pharmacists, being one of the indispensable members of the health care team, have an immense responsibility for counselling patients. Pharmacist consultations provided to patients with diabetes can minimize total healthcare costs in a health maintenance organization (Gerber et al., 1998). Community pharmacists' interventions on improving knowledge and glycaemic control have shown better progress in recovery of diabetics. Continuous counselling and monitoring play an important role in the improvement of glycaemic control (Venkatesan et al., 2012). Intervention by community pharmacists has a beneficial effect on the clinical management of type II diabetes (Mehuys et al., 2011). Assessing the knowledge and practice of community pharmacy personnel can help to design appropriate targeted educational training for the benefit of patients with diabetes (Shrestha et al., 2015).

The community pharmacist KAP previously studied in Tripoli/ Libya showed their knowledge was good. Most pharmacists did not have special training about diabetes but the helpful sources of information used in diabetic education were books and journals, learning from colleagues, published literature and attending lectures (Bisheya et al., 2011). However, community pharmacists in Nepal show that there is poor knowledge and practice toward diabetes. In this study the sample size of 315 community pharmacies, selected by systematic random sampling were surveyed by using pre-validated self-administered questionnaires. The first set of questions evaluated the community pharmacy personnel's diabetes knowledge based on a pre-validated 20-item questionnaire. The second set of 22 questions documented the practice of community pharmacy personnel with respect to diabetes mellitus management. The findings highlighted that 76.5% of respondents had poor knowledge and 86.4 % had negative practice of diabetes mellitus management. Only 26.2% of respondents had good knowledge as well as good practice. 31.4% of respondents had poor knowledge as well as poor practice of diabetic management. The author attributes poor knowledge in the study to a lack of continuing education programmes. Conducting continuing education programmes for pharmacists to enhance their ability to perform pharmaceutical care for diabetes has been shown to increase the participants' knowledge (Chen et al., 2004).

The author suggested that the reason for low level of knowledge and practice among the respondents in this study may be due to the fact that in Nepal, community pharmacy personnel come from diverse educational backgrounds, and thus may not have the intensive knowledge and practice skill required for their profession (Shrestha et al., 2015).

The Diabetes Attitude Scale (DAS) is a well-validated instrument and has been successfully and widely used to measure attitudes in physicians, nurses, dieticians, medical students, and physician assistant students (Donnelly and Anderson, 1990, Fisk et al., 2001). But prior research has provided little information on pharmacists' attitudes toward diabetes and the relationship between educational intervention and attitude change. Pharmacists' knowledge and attitudes toward diabetes could significantly influence patient outcomes.

Given the prevailing concept of a team approach toward diabetes care, only when all health care providers share the same high level of knowledge and positive attitudes could the quality of patient care be ensured (Chen et al., 2004a).

Studies on the attitudes of health care professionals (HCPs) toward diabetes have demonstrated different attitude patterns across different parts of the world. For example, Odili and Oparah (2012) used the DAS-3) and found that although HCPs (nurses, physicians, pharmacists) in Nigeria were in agreement regarding the benefits of diabetes special training programs for HCPs, significant differences with regards to other attitude subscales were noted among participants with nurses demonstrating low attitudes toward seriousness of diabetes, value of tight glycemic control, and patient autonomy (Odili and Oparah, 2012).

However, doctors and pharmacists had more positive attitudes toward the value of tight glycaemic control than nurses. Physicians had stronger attitudes about the seriousness of type II diabetes than nurses and pharmacists. In a cross-sectional study in Yemen, Babelgaith et al. (2013) found that nurses and pharmacists demonstrated weaker attitudes than physicians with regards to the seriousness of diabetes whereas physicians had stronger attitudes toward the value of tight glycaemic control followed by nurses and pharmacists (Babelgaith et al., 2013). In that study, nurses had weaker attitudes on all subscales than physicians and pharmacists and all HCPs surveyed were in agreement regarding the importance of empowering patients toward self-management of diabetes (Babelgaith et al., 2013).

In a multinational survey to assess attitudes of HCPs toward diabetes in eight countries (France, Germany, United Kingdom (UK), Italy, Netherlands, Spain, Sweden, and United States), it was found that physicians tended to have stronger attitudes regarding the seriousness of diabetes and psychosocial impact of the disease (Hajos et al., 2011). Study indicated that diabetes related attitudes of nurses and dieticians in the US were consistently more positive than the attitudes of physicians, especially regarding the seriousness aspects of the disease (Anderson et al., 1991). Anderson and Donnelly (1990) found that physicians tended to view themselves as in control of diabetes with less appreciation of patients' autonomy, unlike nurses and dietitians who valued patients' involvement in decisions related to diabetes (Anderson and Donnelly, 1990). Both studies underscored the importance of interdisciplinary team work in diabetes management and the values of understanding patients' perceptions and emotional status by HCPs to establish therapeutic relationship and enhance patients' coping and emotional well-being (Anderson et al., 1991, Anderson and Donnelly, 1990). Stansfield et al (2007) reported that HCPs underestimated patient autonomy and emotions related to diabetes but overestimated the challenge patients associate with the cost of diabetes (Stansfield et al., 2007). Similar results were noted in a later study in the US which found that HCPs had negative attitudes toward patient ability to handle low blood sugar and the psychosocial aspects of diabetes (Fitzgerald et al., 2008).

The study conducted in Auckland/ New Zealand aimed to quantify and compare knowledge of diabetes including risk factors for diabetes- related complications among the three main groups of primary health care nurses in Auckland:

Practice Nurses (PN), District Nurses (DN) and two specialist nurse groups (Diabetes Specialist Nurses (DSN) and Chronic Care Management (CCM) nurses). The findings showed that most nurses had good knowledge of obesity as a risk factor for type II diabetes mellitus and elevated plasma glucose levels as a risk factor for diabetes-related complications compared with knowledge of cardiovascular risk factors, particularly smoking (Daly et al., 2014). The nurses in Auckland had good knowledge about diabetes that allows patients with type II diabetes to be manged appropriately in primary care. Another reason that nurses have good diabetes knowledge is because they study and follow diabetes guidelines (Ministry of Health, 2008a). National surveys show that patients in New Zealand are increasingly consulting nurses (Ministry of Health, 2008b).

Another study carried out in the North East of England (UK) aimed to describe the views and practices of community pharmacists regarding services for people with type II diabetes. The study found that community pharmacists do not engage in discussions about medication with their patients with diabetes, nor is their potential to provide health promotion advice being met (Abduelkarem et al., 2003). An interesting study conducted in Egypt, Alexandria aimed to examine Egyptian pharmacists' knowledge regarding management of diabetes during Ramadan. It also explored pharmacists' willingness to attend a one day workshop on medication regimen adjustment during Ramada. The study identified considerable gaps among community pharmacists' knowledge of diabetes management during Ramadan in Egypt, a country with a Muslim majority. It also shows willingness among the majority of pharmacists, especially Muslims, to attend a workshop dealing with medication regimen adjustment during Ramadan. Different learning strategies may be of interest for pharmacists who regularly assist Muslim patients, but cannot attend such workshops (Amin and Chewning, 2014).

2.4.3. Antidiabetic medication adherence

Patients with chronic illnesses often experience difficulty in adhering to treatments recommended to them and consequently do not always receive optimal benefit from their prescribed drug therapy (Arifulla et al., 2014). There is a significant relationship between glycaemia (HbA1c levels) and clinical complications with the higher the levels, the greater the complications (Stratton et al., 2000, Selvin et al., 2012). There are many factors that influence glycaemic control, including older age, higher education level, higher patient activity, lower diabetes-related emotional distress, better diet and exercise behaviours, low body mass index (BMI), shorter duration of disease, and knowledge of HbA1c targets, which have all been shown by multiple linear regression to be associated with good glycaemic control (Rogvi et al., 2012). In addition, adherence to medicines may be associated with glycaemic control.

Oral medication for patients with type II diabetes mellitus plays an important role in diabetes care and is associated with a high level self-care behaviour and self-management (WHO, 2003). However, poor adherence to diabetes treatment is common which causes severe health complications and increased mortality (Cramer et al., 2004, Ho et al., 2006). This is reflected for instance by an increase in the risk of cardiovascular diseases, neuropathy, retinopathy, nephropathy and hospitalization rates (Vermeire et al., 2005, Currie et al., 2012, WHO, 1999). Barriers to adherence may consist of complex treatment regimens often along with long-term multi-therapies, side effects due to the medication as well as insufficient, incomprehensible or confusing information or instructions provided by the health care provider. Further barriers challenging adherence could also be related to socioeconomic issues, memory impairment, psychological wellbeing and personal beliefs (Currie et al., 2012, Nam et al., 2011, Odegard& Gray, 2008). Multidisciplinary approaches can support adherence success and can enable a more effective management of diabetes care. Several models for diabetes care have been developed and evaluated (Mehuys et al., 2011). The responsibilities of pharmacists involve for example the long-term supervision, patient education activities, the consideration of medication-related issues (e.g. drug interactions) and of patient needs as well as the optimization of the medicinal treatment and adherence. Studies have shown that pharmacist interventions positively influence health outcomes and patient satisfaction, which are crucial indicators for quality of health care and a key factor for medication adherence (Spinewine et al., 2012).

Low patient adherence is a major barrier to realizing the benefits of medications that have been shown to do more good than harm in clinical trials. Such trials are typically done among patients who are volunteers, and who are followed closely to assure high adherence. Benefits are greatly reduced or nullified in usual clinical practice where adherence rates are low. Interventions to improve adherence have the potential to multiply benefits for patients, but at the time of previous review, no method of helping patients to follow self-administered long-term treatments had been proven effective, actionable, and affordable in usual care settings (Haynes, 2008). Many patients stop taking their medication in the first months following initiation, often without informing their provider, with further attrition over time. In addition, many patients who continue their medication do not consistently take it as prescribed. As a result, adherence rates average around 50% and range from 0% to over 100%, and there is no evidence for substantial change in the past 50 years (Sackett, 1979; Gialamas, 2009; Naderi, 2012).

Medication non-adherence is often defined as taking less than 80% of prescribed doses, although it has to be noted that non-adherence can also include taking too many doses, and it is associated with an increased risk for poor health, adverse clinical events, and mortality. Thus many people who could benefit from medications do not, and much of the public and private investment in health research and health care is undermined. Obviously, low adherence is associated with an increased risk of mortality, and high levels of adherence to drug therapy are associated with positive health outcomes; even high levels of adherence to placebo are associated with lower mortality (Simpson, 2006). Therefore, enhancing medication adherence is a priority and could improve patient outcomes, primarily through the effect of medications, but also possibly through the overall 'healthy adherer' effect. African Americans have lower levels of adherence to diabetes medication than Whites (Trinacty et al., 2009), and, as a result, have worse glycaemic control (Heisler et al., 2007). However, the factors that explain racial disparities in diabetes medication adherence are unknown. One potential explanatory factor is health literacy, or one's ability to understand, engage, and actively apply health information toward the goal of improving one's health (Institute of Medicine, 2004). Racial and ethnic minority groups are disproportionately affected by low health literacy, with an estimated 41% of Hispanics, 24% of African Americans, and 9% of Whites having below basic health literacy skills (National Centre for Education Statistics, 2006).

Adisa et al (2009) studied the factors associated with non-adherence behaviour. The study showed that several factors ranging from dose omission, forgetfulness, high cost and fear of side effects of some oral hypoglycaemic medications, to a collection of difficulties encountered during filling and ingestion of prescribed medications, constitute barriers to medication adherence among patients with type II diabetes. Even in a country such as France with a high level of access to healthcare low levels of medication adherence have been found in type II patients with diabetes. The study conducted in 3,637 persons with type II diabetes found that 39% of patients reported good medication adherence, 49% medium adherence and 12% poor adherence (Tiv et al, 2012).

Many systematic reviews have been published focused on specific (demographic, disease, or medication) populations, interventions, or on an even more specific combination of both. Generally, these reviews reported similar conclusions: some intervention components are potentially effective, but small sample sizes and suboptimal methodology often prevented strong conclusions; the variety of adherence measures limited study comparability; and most studies lacked a theoretical underpinning (van Dulmen 2007).

A study conducted by Osborn et al. (2011) to explore the relationship between low health literacy and suboptimal medication adherence found both more prevalent in minority ethnic groups than majority white populations, Little is known about the relationship between these factors in adults with diabetes, and whether health literacy or numeracy might explain racial and ethnic disparities in diabetes medication adherence. The finding shows that the African American race was associated with poor medication adherence ($r = -0.10$, $p<0.05$). Health literacy was associated with adherence ($r = 0.12$, $p<0.02$), but diabetes-related numeracy and general numeracy were not related to adherence. Furthermore, health literacy reduced the effect of race on adherence to non-significance, such that African American race was no longer directly associated with lower medication adherence (r=0.09, *p*=0.14). The author concluded that diabetes medication adherence promotion interventions should address patient health literacy limitations. The author surmises that health literacy is the key factor to solve the problem of medication adherence (Osborn et al., 2011).

2.5. Chapter summary

To summarize this chapter shows that the effectiveness of clinical pharmacists to control blood glucose is supported by different studies (Aguiar et al., 2016, Collins et al., 2011, Hassali et al., 2015, Omran et al., 2012, Pousinho et al., 2016, Sapkota et al., 2015). However, the impact of community pharmacists on type II diabetes is still in progress or developing. A few studies suggested that community pharmacists might be able to control blood glucose (Ali et al., 2012, Jahangard-Rafsanjani et al., 2015, Mehuys et al., 2011, Venkatesan et al., 2012, Ganawar et al., 2014, Kraemer et al., 2012 ,Paulo et al., 2016, Kjeldsen et al., 2015).

The systematic review found some studies that assessed the effectiveness of community pharmacists in relation to type II diabetes by implementing pharmaceutical care models in different shapes (i.e. counselling, diabetes education, medicine review, quality of life, satisfaction). Some studies strongly agree that community pharmacists can manage glycaemic control for patients with type II diabetes (Mehuys et al., 2011, Kjeldsen et al., 2015,Venkatesan et al., 2012). Another pilot study found that the community pharmacists' involvement can yield improved type II diabetes management, as evident by improvement in primary and secondary outcomes (Ali et al., 2012). However, few studies support, but do not provide clear evidence for, the premise that pharmacist counselling for health care plan beneficiaries with diabetes results in better disease control and improved empowerment to better self-manage this disease (Kraemer et al., 2012) (Paulo et al., 2016) (Gangwar et al., 2014). The duration of studies ranged from five months to twenty four months. However, it seems that the studies exceeding 6 months duration provide significant improvement in HbA1c (Mehuys et al., 2011; Ali et al., 2012), and also a trend toward improvement in HbA1c (Kramer et al., 2012). It has been highlighted by Mehuys et al (2011) that there is still question in sustainability of improvement of glycaemic control in patients with type II diabetes.

Management of type II diabetes can be enhanced by applying clinical guidelines. Self-management is important and can be enhanced in order to improve health for patients with diabetes (if the patients are willing and able). The barriers to self-management comprise: physical barriers (including the nature of their medical condition(s) where people have different needs); and system barriers (including conflicting advice, or a lack of collaborative working, between healthcare and social care professionals in providing services and on-going support for self-management). The research stated that it is essential to address barriers to diabetes self-management and identify strategies to overcome them, and it is important to examine whether there are additional barriers that still exist.

The educational infrastructure implemented in medical and pharmacy schools in Libya is based on the British educational system. This means the English is the first language used in education in both these schools. Therefore, most healthcare professionals, physicians, pharmacists, veterinarian and dentists understand medical terms in academic English. Studies suggest that both developed and developing countries share components of pharmacy practice, but the difference is that developing countries do not apply their learning (with respect to clinical and cognitive services) in practice. The education system is loaded with heavy basic subjects such as analytical chemistry, organic chemistry and so on, with little focus on practice as a pharmacist. There are many studies to improve practice in developing countries and implement pharmaceutical care, they can be successful by simplifying the stages of pharmaceutical care to match the nature of pharmacies in those countries. To enhance clinical outcomes for patients with type II diabetes improving glycaemic control is important. Many studies take an opportunity to implement medicines management or pharmaceutical care from a perspective that the community pharmacist is the most accessible health care professional for patients without appointment. Recently, different strategies to enhance the role of the pharmacist have shown a degree of success.

To understand barriers to self-efficacy among patients with type II diabetes their knowledge, attitude and practice has been studied. Most studies found that patients have relatively poor knowledge, attitude and practice (KAP). In order to improve KAP for patients with diabetes it seems important to understand community pharmacists KAP around type II diabetes. Studies show that pharmacists have good knowledge about type II diabetes and positive attitudes, but they require attention to improve practice. Starting from this view, I shaped my proposal for investigation to ensure pharmacists have proper KAP toward type II diabetes, and then use this to improve patient-related outcomes. My intention is to improve glycaemic control for patients with type II diabetes by applying pharmaceutical care as an intervention in a clinical trial conducted in Tripoli/Libya. Medication adherence studies show that strategies and models to help patients adhere to diabetic medicine still require improvement. Diabetes counselling can be effective, especially in areas of nutrition and improving physical activity. The next chapter outlines the aims and objectives of this investigation in detail.

Research aims and objectives

3.1. Research aims and objectives

This chapter describes the fundamental aims and objectives of the study along with the research questions. The study was organised or structured into four connected stages, in an attempt to achieve the intended clinical outcome (an improvement in glycaemic control).

This short chapter is structured into six sub-headings. The general aims and objectives of the whole thesis are highlighted in **Section 3.1**. Aims and objectives of a community pharmacy premises survey are highlighted in **Section 3.2**. Aims and objectives of a community pharmacist diabetes knowledge and practice survey are provided in **Section 3.3**. Aims and objectives of a training stage to enhance community pharmacist knowledge and practice toward type II diabetes are outlined in **Section 3.4**. The aims and objectives of a randomised controlled trial to improve type II diabetes management are provided in **Section 3.5**. The chapter summary is provided in **Section 3.6.**

Type II diabetes is a chronic health condition associated with significant morbidity and mortality. Many countries are still unaware of the full social and economic impact of diabetes. This lack of understanding is the biggest barrier to effective prevention strategies that could help halt the unstoppable rise of type II diabetes (IDF, 2015). To enable effective management of this increasing problem and to reduce costs, multidisciplinary team approaches to diabetes care seem necessary (ADA, 2009), and over the years, several innovative models of diabetes care have been evaluated (Renders et al., 2001). One of these approaches has included pharmacist cooperation in diabetes management, in-line with greater involvement of the pharmacy profession in patient-oriented activities (Hepler and Strand, 1990, Hepler, 2004). The current study aims to improve type II diabetes management via community pharmacist intervention.

3.1.1. General aims of the whole study

- Improve type II diabetes glycaemic control.
- Development of the role of community pharmacists by engaging them in type II diabetes medicine management or pharmaceutical care.

3.1.2. General objectives of whole study

In order to achieve the above aims, the following objectives were set:

- Assessment of pharmacists' knowledge, attitudes and practices towards diabetes care in community pharmacies within Libya.
- Assessment of type II patients with diabetes' awareness, attitudes and self- management
- Introduction of diabetes non pharmacological management intervention via community pharmacist (randomised controlled trial) to measure level of glycaemic control improvement (FPG and HbA1c)

3.1.3. General research questions of whole thesis

- What is the level of pharmacists' diabetes knowledge, attitudes and practices in community pharmacists in Tripoli, Libya?
- What improvements can be implemented in order to help people with type II diabetes in Tripoli, Libya?

- How can pharmacists' performance with respect to diabetes care be optimised in the context of Tripoli, Libya?

The first stage (pharmacy premises exploration) was centred on collecting data about the structure of community pharmacy premises and pharmaceutical services in Tripoli, Libya. The plan was to distribute 426 copies of a community pharmacy premises questionnaire in Tripoli, Libya (see **Appendix 11**), in order to provide a picture of community pharmacy premises and pharmaceutical services. This then informed plans to improve pharmaceutical services.

3.2. Aims of stage one: structure of community pharmacy premises and pharmaceutical services

- Explore structure of community pharmacies premises in Tripoli, Libya.
- Define existing pharmaceutical services in community pharmacies.

3.2.1. Objectives of stage one

- To describe pharmaceutical services that exist
- To determine the number of community pharmacists and pharmacist technicians that works in each community pharmacy
- To identify diabetes care services that exist in community pharmacy in Tripoli, Libya

3.2.2. Research question

- What is the premises structure of community pharmacies and the pharmaceutical services that exist in Tripoli, Libya?

The second stage (pharmacist knowledge, practice and recruitment) was centred on reaching pharmacists by distributing self-competition questionnaires to community pharmacies located in Tripoli, Libya. This stage was divided into two steps, the first being a pilot stage. The pilot involved distribution of 53 copies of a self-completion questionnaire (**Appendix 8**). Then, the main questionnaire titled community pharmacist diabetes knowledge and practice toward type II diabetes (**Appendix 9**) was distributed to 125 community pharmacies.

3.3. Aims of stage two: diabetes knowledge and practice toward type II diabetes among community pharmacist in Tripoli, Libya (piloting and main study)

There were two aims for the piloting stage:

- To recruit as many as community pharmacies as possible for the intervention study
- To test questionnaires in terms of response rate and understandability.

The aims of the main study were:

- To recruit pharmacists who were happy to volunteer and;
- To explore pharmacists knowledge and practices towards diabetes II care.

3.3.1. Objectives of stage two

The objectives can be categorised as following:

- To evaluate the level of pharmacists' diabetes knowledge and practice.
- To randomly sample from the list of geographical areas in which community pharmacies were surveyed.

3.4. Aims of stage three: enhancing community pharmacists type II diabetes knowledge and practice (training stage)

The third stage was centred on training community pharmacists to improve diabetes knowledge. The community pharmacies were randomised into control and intervention groups. The diabetes educational materials (**Appendix 12**) along with diabetes knowledge test (**Appendix 13**) provided to intervention group.

- Development of role of community pharmacists towards type II diabetes management.
- Enhancement of community pharmacists' diabetes knowledge and practice in order to increase counselling skills for people with type II diabetes.

3.4.1. Objectives of stage three

In order to achieve to the above aims the following objectives were sets out:

- Assess diabetes knowledge and practice before educational intervention (**Appendix 12**).
- Determine the level of diabetes knowledge and practice after educational intervention for the intervention pharmacies.

The fourth stage (an intervention study) was centred on implemented a randomised controlled trial. The trial focused on type II diabetes education and counselling provided to people with type II diabetes. The patients were recruited via community pharmacies randomised into eighteen control community pharmacies and 22 intervention community pharmacies.

3.5. Aims of stage four: Type II diabetes management intervention study

- To improve glycaemic control via the community pharmacist intervention.
- Enhance effectiveness of community pharmacist diabetes medicine management by engaging pharmacists to assist patients with diabetes to improve their diabetes knowledge, self-management and attitudes.

3.5.1. Objectives of stage four

In order to achieve the above aims the following objective set:

- Evaluate diabetes knowledge in both control and intervention groups before starting the intervention to set a baseline (**Appendix 15**).
- Assess diabetes self-care behaviour in both groups before starting the intervention (**Appendix 16**).
- Determine diabetes attitudes in both groups and to set a baseline (**Appendix 17)**
- Determine FPG and HbA1c in both groups and to set a baseline.

3.5.2. Research questions

- How to improve blood glucose control among patients with type II diabetes?
- What is the role of community pharmacists to enhance diabetes knowledge, self- management and attitudes (via the intervention)?
- What is the clinical impact of the intervention on the patients with type II diabetes?
- Can the proposed intervention be successful in this challenging context?

3.6. Chapter summary

To sum up, the chapter provides the key aims and objectives for each stage of the study. The overall aim of study was to improve type II diabetes management by co-operation between community pharmacists and patients with diabetes. To achieve the intended outcomes it was important to understand the level of diabetes knowledge and practice among community pharmacists. It was fundamental to explore community pharmacists' premises to shape the intervention in the context of available pharmaceutical services; then to ensure that the intervention study was implemented correctly it was vital to train pharmacies in the intervention group. After that the intervention was implemented. In Chapters Four, Five, Six and Seven the four stages will be described in detail, including (in each case) methods, results, discussion and conclusion.

Structure and pharmaceutical services exist in community pharmacies in Tripoli/Libya

This chapter is divided into six sections. The introduction, **Section 4.1**, outlines the structure of community pharmacy in developed and developing countries. The methods and design of the study are described in **Section 4.2**. The statistical results are provided in Section 4.3, the discussion in **Section 4.4** and the conclusion in **Section 4.5**. The chapter summary provided in **Section 4.6**

This chapter was created to provide the reader with information about the structure and organisation of community pharmacies in Tripoli/Libya, because there is a lack of existing documentation or data. The nature of pharmacy services in Tripoli must be understood before the thesis moves on to describe how community pharmacy might improve the care of patients with Type II diabetes, by improving pharmaceutical care or medicines management.

4.1. Community pharmacy premises structure

The aim of this chapter is to explore the structure of community pharmacies premises in Tripoli/Libya and to define the existing pharmaceutical services. In a number of countries, community pharmacy is moving through a period of fundamental change. In the UK, community pharmacists were known in the past as chemists (PSNC, 2016). Community pharmacies can be found on the high street, at the heart of the most rural villages and in the centre of the most deprived communities. Many are open long hours when other health care professionals are unavailable. There are several different types and sizes of community pharmacies, ranging from the larger multiples to the small individually owned pharmacies. The traditional role of the community pharmacist as the white coat wearing healthcare professional who dispenses prescriptions written by doctors has changed. In recent years community pharmacists have been developing clinical services in addition to the traditional dispensing role to allow better integration and collaborative working with other health and social care providers; and more importantly to deliver better patient care (PSNC, 2016).

Community pharmacists are the health professionals most accessible to the public in many countries. They supply medicines in accordance with a prescription or, when legally permitted, sell them without a prescription. In addition to ensuring an accurate supply of appropriate products, their professional activities also cover counselling of patients at the time of dispensing of prescription and non-prescription drugs, drug information to health professionals, patients and the general public, and participation in health-promotion programmes. They maintain links with other health professionals in primary health care. Today, an increasingly wide range of new and analogous products are used in medicine, including high-technology biological products and radio-pharmaceuticals. There is also the heterogeneous group of medical devices, which includes some products analogous to medicines, some of which demand special knowledge with regard to their uses and risks (e.g., dressings, wound management products, etc.). Pharmacists have progressively undertaken the additional task of ensuring the quality of the products they supply (WHO, 2016).

The pharmaceutical sector and its overall conditions in developing countries are under- researched. There is a scarcity of studies and information on pharmaceutical health services systems researched (Fathelrahman et al., 2016). The definition of pharmacy and pharmacists have been subjected to numerous changes throughout the history of the pharmacy profession and historically many names have been used to describe those who practice pharmacy or who are involved in certain aspects related to pharmacy. Community pharmacists provide an established and visible network, extending to remote areas, of easily accessible health care professionals (Fathelrahman et al., 2016). It is recognised that in most developing countries, pharmaceutical services are virtually exclusively carried out from the institutions or premises at which the worker is based. Little attempt has, therefore, been made to explore domiciliary services (IPF, 1998) i.e. those provided in the patients' home. There is an extensive network of over 600 community pharmacists in Tripoli/ Libya. We thought it a golden opportunity to explore the role of these pharmacies in diabetes education since diabetes care was currently concentrated in only a couple of specialist centres (Bisheya et al., 2011).

Research suggests that the primary health care consultation rate in Australian pharmacies may be as high as 43 million per year. The consumer can consult a pharmacist without an appointment and with minimal waiting times. This is where community pharmacists can assist. Pharmacists are nationally recognised as providers of long-term care for people with diabetes and it is logical that they should help the Australian health care system cope with the burgeoning issue of type II diabetes and its intensive, evidence-based management. Moreover pharmacists should be identified as part of the diabetes care team (Krass et al., 2004). Every day about 1.6 million people visit a pharmacy in England NHS (PSNC, 2016).

Community pharmacies are an under-used resource: many are now open 100 hours a week in the UK with a qualified pharmacist on hand to advise on minor illnesses, medication queries and other problems. We can capitalise on the untapped potential, and convenience, that greater utilisation of the skills and expertise of the pharmacy workforce can offer (Loader, 2014).

Recently, the role of the pharmacist developed in UK and cited by Twigg (2013, p2) that "*One of the most important functions of a pharmacist at this time, and until the founding of the National Health Service (NHS), was to advise and treat patients who could not afford to see a general practitioner (GP). If someone wanted to see a GP, they had to pay for the consultation and then pay for the medicine that either the GP or the pharmacist would dispense. Patients who saw a pharmacist only had to pay for any medicines which the any medicines which they recommended. In a time when universal healthcare had not yet been established and wages were low, this was the only option available to many people*".

4.2. Methodology

Sampling was started based on WHO data (WHO, 2007) as shown in the **Table 4.1** that the number of private pharmacies in Tripoli/Libya was 426. However, there was no list of pharmacy locations, structure or the kind of services that exist. It was decided to collect data from all of the pharmacies in Tripoli to see how many now exist, what kind of services they provide and their structure.

Table 4.1: Total number of private pharmacies and other clinics in Libya

Source: (WHO, 2007)

Private Sectors						
No	Name of Shabiat	In patient clinics	No of beds	Outpatient clinics	Dental clinics	Pharmacies
1	Albetnan	1	20	7	2	38
2	Derna	2	12	7	4	38
3	Al-Gebal-Alakhdar	0	0	11	4	42
4	Almarege	0	0	9	3	33
5	Benghazi	16	272	78	41	250
6	Al-Wahat	0	0	10	4	27
7	Al-Kufra	0	0	3	1	5
8	Sirte	2	26	6	5	45
9	Al-Jufra	0	0	3	1	12
10	Misurata	9	112	27	25	81
11	Al-Merghip	11	120	33	5	39
12	Tripoli	27	502	126	124	426
13	Joufara	1	120	26	7	135
14	Alzawea	3	82	32	6	79
15	Al-Gebal-Lgharbi	0	0	16	7	55
16	Naloot	0	0	2	2	20
17	Sebha	4	25	7	12	57
18	Ghat	0	0	0	0	2
19	Morzig	0	0	2	1	9
20	Wadi-Alhiat	0	0	2	2	16
21	Wadi-Alshati	0	0	6	2	29
22	Al-Nequt-Alghmis	8	70	18	1	64
	Total	84	1361	431	259	1502

4.2.1. Methods

The study was designed to explore the structure of community pharmacies premises and pharmaceutical services that exist in Tripoli/Libya. There is no sampling method used because a census of current pharmacists was intended. A total of 426 copies of the self-completion questionnaire (see **Appendix 11**) were distributed by hand in July 2015. The questionnaire was distributed by hand.

4.2.2. Justification of Methodology

This survey aims to provide description of community pharmacies premises and pharmaceutical services that exist in Tripoli/ Libya. The data relating to this aim were collected using the methods discussed below.

4.2.2.1. Self- administered questionnaire

The questionnaire was presented to the respondents by the representatives of another pharmacist and the purpose of the inquiry was explained. The respondents were then left alone to complete the questionnaire, which was picked up later. This method of data collection can ensure a high response rate, accurate sampling and minimum of investigator bias, while permitting investigator assessments, providing necessary explanations (but not interpretation of questions) and giving the benefit of a degree of personal contact (Opeenheim, 1992). The questionnaire was adapted from pharmaceutical needs assessments (PNA) with amendments that fit community pharmacies in Libya as a developing country (see **Appendix 11**). Permission to adapt the PNA questionnaire was sought from the PSNC.

4.2.2.2. *Structure of questionnaire*

The survey was adapted from the pharmaceutical needs assessments (PNA) survey in England where there is “a statutory responsibility to publish and keep up to date a statement of the needs for pharmaceutical services for the population” (Sangha and Rowson, 2015: 7). The structure of community pharmacy in Tripoli/Libya was explored in order to describe the infrastructure of pharmacies in Libya. In addition, it could help other researchers to shape new pharmaceutical services. The information was collected to explore the premises and pharmaceutical services available in community pharmacies in Libya, but there was no intention (at that stage) to make any change or improvement. The aim of this chapter is to provide the reader with structure of community pharmacies. Another reason for this kind of survey was to establish the representativeness of participants the trial stage. The only information known was that were 426 pharmacies in Tripoli (WHO, 2007), but there is no published list of pharmacies (or services). Therefore, the exploratory study provided essential background information.

The questionnaire was structured into four sections (**Appendix 11**). Section one provided data about pharmacy premises consisting of:

- Name of pharmacy
- Geographic area (i.e. the name of area that the pharmacy was located in)
- Name of street (if applicable, some places do not have street names)

- Type of pharmacy (i.e. whether the pharmacy was private or public: public pharmacies supply free medicines, but private ones sell them)
- Type of location (whether located in commercial or residential places)

This gives an idea about how accessible community pharmacies are to people. Then to understand availability of staff in the pharmacy to help patients these questions were asked:

- Number of staff working in the pharmacy
- Number of community pharmacists working in each pharmacy
- Number of community pharmacy technicians

Section two asked about opening and closing hours of the community pharmacy on each day of the week to understand availability of pharmacy services. The next section provided data about availability of consultation services:

- Asking about availability of a consultation area in the pharmacy
- If the respondent answered yes to this, then further questions:
    - Where is the consultation area? Whether on or off the premises?
    - Have you got washing facilities in the consultation area?
    - Whether people attending consultations have access to a toilet?

It has been supported by different studies that the consultation area is essential for medicines use reviews (MURs), which are part of medicines management. Areas should be designed to allow confidential consultations and a place where both the person receiving MUR services and the registered pharmacist providing those services are able to sit down together and talk at normal speaking volumes without being overheard by any other person (Local Government Association, 2013) (Everden, 2015). This survey was adapted from the PNA in England, which reported that over 90 per cent of pharmacies have a private consultation room and many have already taken on a wider public health role, for example running weekly clinics to help people lose weight, stop smoking or to monitor blood pressure or cholesterol (Local Government Association, 2013). From this perspective the questions were adapted to investigate whether in Libya as a developing country these strategies had been initiated.

Section four asked questions about pharmaceutical services provided. The section divided into three topics:

- Essential services: can be defined as services that should be available in each community pharmacy, services include dispensing, promoting healthy lifestyles and signposting which all community pharmacies must provide (Everden, 2005) (Prescribing and Primary Care team, Health and Social Care Information Centre, 2013). This topic asked questions about:
    - Whether the pharmacy dispensed appliances or not?
    - What type of appliances (if any) dispensed?
    - Whether the pharmacy provided repeat dispensing services?
    - The average number of monthly repeat items (if any)?
    - Whether the pharmacy disposed of unwanted medicine?
    - If the pharmacy disposed of unwanted glucose strips?

- Advanced services - questions about:
    - whether or not providing diabetes medicine management and glucometer
    - If applicable, which kind of diabetes medicines management was provided:
        - Patient education
        - Initial assessment and monitoring
        - Check height, weight and calculate BMI
        - Check smoking status
        - Glucose control
        - Dietary advice
        - Referral for management of glucose control

These questions about diabetes medicines management were introduced by the investigator and not part of the original PNA questionnaire (PSNC, 2013) (Everden, 2015). The original PNA did ask questions about components of medicine management including:

- Medicine use review
- New medicines services
- Appliance use review
- Stoma appliance review
- Disease specific medicines management

Disease specific medicines management has been defined by The National Health Service Act (2006, p:17) as "*a service underlying purpose of which is for a registered pharmacist to advise on, support and monitor the treatment of* *patients with specified conditions, and where appropriate to refer the patient to another health care professionals*". In developing countries this is possible but not as advanced as in developed nations (Smith, 2016) . There might be discussions with a patient and advice from the pharmacist but no active interventions. Simply, the pharmacist might provide advice but state that a doctor should be consulted or recommend self-monitoring using simple equipment, for example, a blood pressure monitor or glucometer.

Questions were asked about disease specific medicine management that the community pharmacy might provide or be willing to provide:

- Allergies
- Alzheimer's
- Depression
- Diabetes type I
- Diabetes type II
- Epilepsy
- Heart failure
- Hypertension
- Parkinson's disease

4.2.3. Data Analysis

The data has been analysed with the use of Statistical Package for Social Sciences (SPSS) and Excel. Descriptive statistics were used for demographic characteristics, opening hours among community pharmacies, availability of consultation area and providing essential services. Tables and bars were used illustrate the descriptive statistics. Tables were used to describe premises structure by using frequency and percentages. Similar methods of presentation were applied to other parts of analysis.

Bar charts used to highlight pharmacies that providing or were willing to provide enhanced services. Pie charts used to indicate frequency of premises details, consultation service and pharmaceutical services.

4.3. Results of the community pharmacy survey in Tripoli/ Libya

A total of 426 questionnaires were distributed by hand; of these, three hundred and eighty nine were returned a total of 37 refused participation for different reasons; 10 participants stated a lack of time, whilst 17 neglected to fill in the questionnaire and were not interested in the study and 10 missing to collect. The statistical results of this survey can be categorised into four parts:

- demographic information about community pharmacy premises
- information about opening and closing hours of community pharmacies
- consultation area availability and facilities
- information about pharmaceutical services

4.3.1. Demographic profile of community pharmacist premises

Table 4.2 shows the responses of 389 self-completion questionnaires. Three quarters were private (341, 88%) rather than public pharmacies (48, 12%). Most pharmacies were located in commercial (212, 54.5%) rather than residential areas (177, 45.5%).

Table 4.3 shows the number of staff working in each pharmacy ranged from 2-9 and 93 pharmacies reported that 5 people worked in each pharmacy. Only 2 pharmacies reported that 9 people worked in each pharmacy. **Table 4.2** shows that the number of community pharmacists working in 386 pharmacies ranged from two to five. The highest number of pharmacies (166) reported that each pharmacy had two community pharmacists working. For community pharmacist technicians, 156 pharmacies reported that two technicians worked in each pharmacy. The total number of community pharmacists working in 386 pharmacies was 858 and the total number of community pharmacist technicians working was 760 in 378 pharmacies.

Table 4.2: Community pharmacy premises structure

Description	Frequency (Percent)
Total number of respondents	389
Type of pharmacy: Private Public	 341(88%) 48(12%)
Location of pharmacy: Commercial Residential	 212(54.5%) 177(45.5%)

Table 4.3: Total number of staff working in each pharmacy

No of pharmacies	Number of staff working in each pharmacy	
59	2	118
76	3	228
91	4	364
93	5	465
51	6	306
17	7	119
2	9	18
389	36	1618

Table 4.4: The distribution of community pharmacists and technicians among pharmacies

No of pharmacies	No of community pharmacist	No of pharmacies	No of community pharmacist technician
89	1	123	1
166	2	156	2
97	3	75	3
29	4	20	4
5	6	4	5
386		378	

4.3.2. Opening and closing hours of community pharmacies in Tripoli/ Libya

This result shows the accessibility for community pharmacies in Tripoli Libya. Most pharmacies were open between 85 and 90 hours weekly (155, 44%). A quarter was open between 75 and 80 hours (92, 24%) and between 70 and 75 hours (86, 22%). A lower number were open between 90 and 100 hours (56, 14%) see (**Table 4.5**).

Chart 4.1 shows opening hours of pharmacies on weekdays (Saturday till Thursday) by city district. Most community pharmacies were open between 9:00 am and 11:00 pm (174, 45%). The lowest numbers were open early in the morning (7:30 am until 7:30 pm: 37, 10%) or for the hours 9:00 am-10 pm (37, 10%). **Table 4.6** describes the working hours on Friday, which is public holiday in Libya. The lowest number of community pharmacies is open in the morning at 10:00am (37, 9%). The largest number of pharmacies opens at 4:00 pm (175, 45%).

Table 4.5: Number of hours of pharmaceutical services available each week in Tripoli, Libya

Number of hours	Number of pharmacies	Percentage
More than 70hrs and up to 75hrs	86	22
More than 75hrs and up to 80 hrs	92	24
More than 85 hrs and up to 90 hrs	155	40
More than 90 hrs and up to 100 hrs	56	14
Total	389	100

Table 4.6 Number of community pharmacies open in the morning and evening on Friday

Private and public pharmacies opening hours in the morning and evening on Friday		
The pharmacies beginning hours to open whether in morning or afternoon	Number of pharmacies	Percentage
10:00 am	37	9
4:00 pm	175	45
5:00 pm	123	32
5:30 pm	54	14
Total	389	100.0

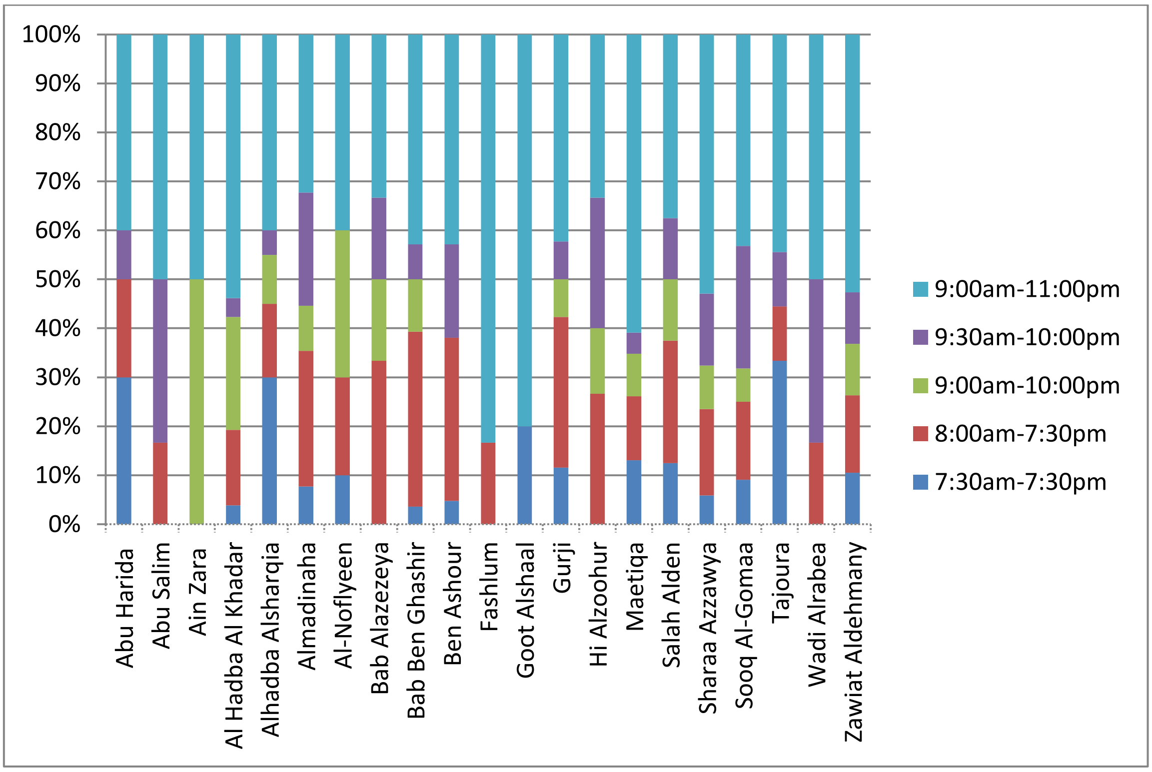


Chart 4.1: Opening hours of pharmacies on weekdays (by district**)**

4.3.3. Availability of consultation area

Table 4.7 and **Chart 4.2** show that most community pharmacies do not have a consultation area (353, 92%) and only 8% (32) have a consultation area. When present, consultation areas are usually on (30, 94%) rather than off (2, 6%) the premises. Hand wash facilities are available in one-third of consultation areas (11, 34%) or close by in some cases (2, 6%). Two-thirds of consultation areas do not have hand wash facilities (19, 59%).

Table 4.7: Availability of consultation area in community pharmacy

Consultation area	Frequency	Percent
Do you have consultation area? Yes No	 32 353	 8% 92%
Is the consultation area located? On premises Off premises	 30 2	 94% 6%
During consultation are there any hand wash facilities? No hand washing Hand washing facility in consultation room Hand washing facilities close to consultation room	19 11 2	59% 34% 6%
Total	389	100

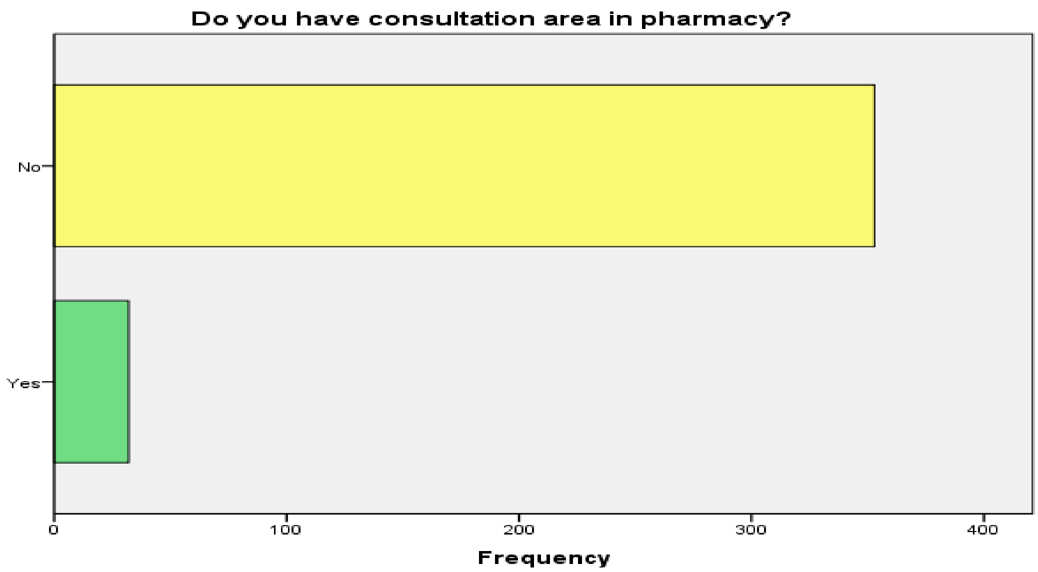


Chart 4.2: Availability of consultation area in community pharmacy in Tripoli

4.3.4. Essential services

Table 4.8 shows that a minority of pharmacies dispense appliances (168, 46%). The most appliance that found dressing at (124, 32%) and just (25, 7%) have all appliances in pharmacies. For repeat prescription (219, 57%) provide repeat dispensing. Half of pharmacies dispense repeat prescription with monthly average from zero till 10 prescriptions at (193, 50%). Most community pharmacies do not dispose medicine (367, 95%) and also do not dispose unwanted glucometer strips (361, 95%).

Table 4.8: availability of essential services among community pharmacies in Tripoli/ Libya

Items	Frequency	Percentage
Dispensing appliances Yes No	 168 200	 46% 54%
Type of appliances dose the pharmacy dispense: • All types • All excluding stoma appliances • All excluding stoma and incontinence appliances • Just dressing	 25 6 4 124	 7% 2% 1% 32%
Dose the pharmacy provide repeat dispensing? Yes No	 219 168	 57% 43%
Average of monthly repeat dispensing 0-10 11-20 21-30	 192 23 6	 87% 11% 2%
Do you dispose unwanted medicine? Yes No	 20 367	 5% 95%
Do you dispose unwanted glucometer strips? Yes No	 19 361	 5% 95%
Total	389	100

4.4. Discussion

The United Nations (UN) classifies countries into developed (or industrial) and developing based on their level of economic and industrial development. A sub-group of developing countries are designed as least developed countries (LDCs) (Smith, 2001). These are countries with very low per capita income (Smith, 2001). The World Health Organisation has identified particular problems in developing countries in relation to the supply and use of drugs. In response to these difficulties, the WHO believes that pharmacists can make an important contribution in health care, by promoting the safe and appropriate use of Medicines (WHO, 1988).

Pharmaceutical services in developing countries face some specific challenges unlike those faced by pharmacists in the developed world. In most developing countries, lack of appropriate and good-quality medicines are the most common problem encountered (Farris et al., 2005). Irrational use of medicines and weak regulatory enforcement of drug sales are also serious issues in developing countries. For example, findings from a survey conducted in a rural region of Ghana revealed that drug retailers in five pharmacy shops were found to have little or no training in pharmacy; the population bought drugs without prescriptions; the staff of these shops contributed to drug misuse by providing misinformation about drugs and selling drugs according to popular demand (Wolf-Gould et al., 1991).

The pharmaceutical service in Libya has been poorly documented. The current study reveals that the consultation areas are scarce in community pharmacies in Tripoli. Out of 389 pharmacies, 32 (8%) pharmacies have had consultation areas compared with a Northumberland survey where (out of 75 pharmacies) 71 (99%) had a consultation room, and 56 (79%) could access hand washing facilities, either in the consultation area or close to it (Everden, 2015). According to Everden (2015) a consultation room is essential to provide advanced services, e.g. Medicine Use Reviews (MURs) and many locally commissioned services. However, simple interventions such as checking patient blood glucose levels, or hypertension, or giving advice could be done even without dedicated consultation areas. There is no fundamental barrier to providing pharmaceutical care, due to a lack of consultation areas. However, the availability of consultation areas can offer some advantages. These consultation areas allow the patient and the pharmacist to interact in a setting that respects the privacy of the patients. The patient's consultation areas, when used to discuss medication and other health issues, enhance the professional interaction and relationship between the patient and the pharmacist. It also facilitates and encourages patients to request and benefit from the professional input and counselling they require from the pharmacist Everden (2015).

The requirement to have a consultation area, within a pharmacy, already exists in many countries including Scotland, The Netherlands and Australia. It is widely recognised that patient consultation areas are a beneficial resource for patients Everden (2015). The availability and use of such areas aims to improve patient confidentiality and ultimately patient outcomes. A patient consultation area that is correctly designed and used allows the patient and the pharmacist to interact in a setting that respects the privacy of the patient. The patient consultation area, when used to discuss medication and other health issues, enhances the professional interaction and relationship between the patient and the pharmacist. It also facilitates and encourages patients to request and avail of the professional input and counselling they require from the pharmacist. In addition, a designated area within a pharmacy, specifically for patient consultation, will enable the pharmacist to become a more integral part of the multidisciplinary team involved in a patient's care. The confidential and personal nature of a consultation, within a consultation area, has huge potential to improve patients' health by increasing patient education, encouraging the appropriate and rational use of medication, and thus reducing medication-related problems (The Pharmaceutical Society of Ireland, 2010).

Repeat prescribing in Libya is carried out by patients going to hospital to see a doctor to prescribe the medicine then going to a pharmacy to have the medicine dispensed. For long term disease such as diabetes the patients have a special green card. The patients go to a special diabetic hospital where both the doctor and dispensing pharmacist work. If the patient wants to collect their medicine from a community pharmacy (called a private pharmacy in Libya) they must first see a doctor to obtain a prescription. Some patients, especially elderly people, obtain their medicine by showing the packaging to the pharmacist and ask to buy their medicine without going to see a doctor. There is repeat dispensing but not organised systematically as in the UK.

In the UK, repeat prescribing accounts for approximately 75% of all general practice prescribing and many patients are on poly-pharmacy regimes. Current practices for generating repeat prescriptions are generally acknowledged to provide inadequate control. This results in over-prescribing, stockpiling of drugs and infrequent review of therapy, which may lead to failure to identify issues such as drug interactions, adverse drug reactions, poor compliance and inappropriate treatment (Bond, 2016). An early randomised study demonstrated that pharmacists can appropriately manage repeat prescribing with a resultant increase in the detection of problems such as adherence problems and identification of adverse (Bond, 2016). There is also a reduction in drug wastage and cost avoidance by patients, as well as improved clinical benefits (Bond et al., 2000). Repeat dispensing involves authorising a community pharmacist to dispense repeat prescriptions for a patient, over an agreed time period, without the need for the patient to go back to the doctor (Morecroft et al., 2006).

The data shows that pharmacy opening hours reached at maximum of 91 hours per week, and long hours were routine. In comparison, the UK has core pharmacy opening hours of 40 hours a week, unless a reduction is agreed by NHS England. These core hours are provided as an essential pharmacy service. The UK also has a number of 100 hour pharmacies, but these are in the minority Everden (2015).

4.5. Conclusion

Three hundred and eighty nine community pharmacies participated in the study. The majority of community pharmacies were private therefore the patients have to pay for their medicine. Most pharmacies were open from 9:00am until 11:00pm. The majority of pharmacies do not have a consultation area. Many pharmacies do not dispose of waste medicines or glucometer strips. The majority of pharmacies did not have a consultation area. Many pharmacies did not dispose of waste medicines or glucometer strips. This information helped to shape the clinical trial in terms of accessibility of community pharmacies, however, the fact that there were few consultation areas was not a barrier to further research.

4.6. Chapter summary

This chapter provides the reader with a basic structure of community pharmacies in Tripoli, Libya; this includes premises characteristics and pharmaceutical services offered. One of the most significant changes in health care delivery in recent years has been recognising the importance of patients' individual biographies. Pharmaceutical services reflect this, as their focus shifts from being largely centred on drug-product to a concern for the patient as an individual, as exemplified by international recognition of the pharmaceutical care concept (Harding & Taylor, 2016). As Libya is a developing country the data shows that there are deficiencies in some pharmaceutical services considered essential elsewhere, for example, disposing of waste medicines and availability of consultation areas. However, long opening hours provide good patient access compared to a 40 hour norm in the United Kingdom (NCC, 2015).

In **Chapter Five** community pharmacies knowledge and practice with respect to type II diabetes is explored. This builds on the structural information provided in **Chapter 4**, by providing more detail about care processes.

Exploration of community pharmacist diabetes knowledge and practice toward type II diabetes in Tripoli, Libya

Introduction

This chapter is divided into six sections: a brief introduction about pharmacists' knowledge and practice toward type II diabetes care is provided in **Section 5.1**. In the next **Section 5.2** the methods are described. Then, statistical data analysis is in **Section 5.3.** The discussion is provided in **Section 5.4** and the conclusion in **Section 5.5**. The summary of key points is found in **Section 5.6**.

Abstract

Aims/objectives: To explore community pharmacists' knowledge and practice with respect to type II diabetes care in a developing country. This assessment is the first stage of an intervention to improve the delivery of care and will inform the design of training materials prior to a clinical trial.

Research design and methodology: The study was carried out as an exploratory study in 125 community pharmacies located in diverse areas of Tripoli in Libya, which is Arabic-speaking. These pharmacies were chosen through purposive sampling and a self-completion questionnaire was distributed by hand. The project was approved by a Research Ethics Panel at the University of Bradford.

Results: One hundred and eight questionnaires were returned, a response rate of 86%. There were roughly equal numbers of males (55) and females (53). The mean (± sd) number of years' experience as a community pharmacist was 5.9 (±5.13). The community pharmacists had good knowledge of diabetes with average scores of 21/29 (±3.18). The results show that the most common things pharmacists (always) give information about are: how to use the medicine (n=80/103, 79%); what the medicine is for (n=61/101, 61%); when to use medicines (n=54/98, 56%); and special storage instructions (n=47/99, 48%). On the other hand, when comparing with other Standard Operating Procedures (SOPs), the lowest percentages of provision (always) include: discussing information about medicines with the patient (not just giving) (n=12/101, 12%); checking that patients have any information they need about medicines (n=15/99, 15%); and offering patients information about medicines before they are prescribed (n= 17/100, 17%).

Conclusion/discussion: The community pharmacists had good knowledge about diabetes, which could be a foundation for more clinical practice. Basic provision of information for patients appeared to be good; however, there were opportunities to enhance the level of care provided.

5.1. A brief introduction about pharmacists' knowledge and practice toward type II diabetes care

Pharmacists' particular body of knowledge and skills relates to the use of medicines and falls into board areas. Firstly, all pharmacists share scientific knowledge about medicines and their clinical applications and uses. Secondly, there is a body of knowledge about how to make best use of medicines, both applied to the needs and circumstances of individual patients (for example: selection of delivery system, advice and usage) and in terms of overall efficacy and effectiveness (such as development of formularies, organisation of supply). This knowledge is based primarily in the biological and physical sciences but draws crucially on various social science disciplines, including psychology, sociology and economics (Mays, 1997).

The traditional medication dispensing function undertaken by community pharmacists in the UK over the last 30 years has become more efficient as a result of advances in information technology, automation and the provision of medicines in original packs (Department of Health, 2005). Consequently, as professional qualification now entails a four year undergraduate education course and one year's workplace training, the government and wider community have repeatedly identified that the clinical knowledge and skills of the community pharmacist need to be utilised to better effect to benefit individual patients and reduce the burden on other healthcare professionals (Department of Health, 2005).

Assessing the knowledge and practice of community pharmacy personnel can help to design appropriate targeted educational training for the benefit of patients with diabetes. This stage of the current research was built on a previous study carried out in Tripoli, Libya between 2001 and 2002, which was centred on evaluating the knowledge and attitudes of community pharmacists toward diabetes care (Bisheya et al., 2011). The results showed that community pharmacists have good knowledge. The study had some limitations. Convenience sampling has its inherent limitations; however, the included pharmacists were likely to be fairly representative of the target population based on the sample size (146 out of 700) and the fact that they were based in all parts of the city and the response rate was very high.

In addition, there seemed to be fairly uniform size, distribution, staffing levels and professional activities among pharmacies in the city. The survey employed mostly closed ended questions, multiple choice questions and 3 to 4 point scales to simplify the answers. The knowledge questionnaire was basic (Amoah et al., 2000, Al-Fadhel and Naylor, 2002) as the aim of the study was to assess pharmacists' ability to educate rather than their academic performance. Hence it was administered in an Arabic version (Al-Fadhel and Naylor, 2002) as this would be the language that pharmacists would use to communicate with the patients even though they may have been educated in English. The study is in grey literature and the standard of English is poor. However, it is a good source of information and it can be used as a starting point to shape the current intervention study. From this foundation, a questionnaire was designed to explore knowledge and practice among community pharmacists in Tripoli, Libya in order to update the information and also to recruit community pharmacies and pharmacists for a subsequent clinical trial.

Where patients were not involved in a particular service, the pharmacist has been found to be used primarily by patients to gain information specifically about drug interactions and side effects, with fewer patients wanting to discuss their condition, adherence and impact on their lifestyle (McAuley et al., 2009). The study carried out by Twigg et al., (2013) indicated that many patients saw the pharmacist as having the knowledge and time to discuss their medicines and condition but as being impeded from doing so by the community pharmacy environment. The barriers to patients asking pharmacists questions appear to fall into two categories: patient and pharmacist-related (Krueger and Hermansen-Kobulnicky, 2011). The patient-related barriers include: fear or embarrassment, lacking initiative, having no need for any information and time constraints. The pharmacist-related barriers include being seen as less approachable and not being seen as such a credible or trustworthy information source. In UK study the participants highlighted their trust in the physician to provide most of their information and also raised the fear that by speaking to the pharmacist they might be in some way going against their doctor (Twigg et al., 2013). Specific patient groups have highlighted where they view the role of the pharmacist and this largely depends on their personal experience. Patients also have an idea about how far this role extends to the greater management of their condition with most indicating that they still need the physician to be involved in their care if they are to trust what the pharmacist is doing for them (Twigg et al., 2013). The author stated that the information is important to the the government's vision for pharmacy is to be realised in patients with chronic conditions (Twigg et al., 2013).

5.2. Methodology

The aims of this stage are to explore community pharmacists' knowledge and practices towards type II diabetes care. The reason for completing a review of pharmacists' diabetes knowledge and practices is to gain understanding of their weaknesses and strengths. This is recognised as a descriptive stage; therefore, the study can be seen as self-completion questionnaire (Appendix 1 and 2) in order to generate the relevant data that can both inform and provide a clear picture regarding the current situation of the study problem.

The current study explores community pharmacist knowledge and practice toward type II diabetic management. The questionnaire has been piloted because it is highly recommended to pilot questionnaires in successful research (Oppenheim, 1992). Pilot work may be costly, but it will save time and money in the end. With this noted, it is true to state that 'pilot work can produce some nasty surprises, but it is never dull' (Oppenheim, 1992). Therefore, pilot work is considered an intellectual challenge in the conceptualisation and re-conceptualisation of the key aims of the study, as well as in making preparations for field work and analysis so that not too much will go wrong and nothing will have been left out. The questionnaire was first distributed to 53 participants and then to 125.

5.2.1. Methods of Study

This stage was built on a study carried out in Tripoli, Libya, between 2001 and 2002, which was centred on evaluating the knowledge, attitudes and practice of community pharmacists toward diabetes care (Bisheya et al., 2011).

The stage was completed in two steps:

First step: piloting phase. The pilot was carried out for the following reasons:

- To recruit as many as community pharmacies as possible for the intervention study
- To test the questionnaires in terms of response rate and understandability

Second step: main study of community pharmacists' type II diabetes knowledge and practice. For the same above reasons to recruit more community pharmacists except for making sure that questionnaire is easy to understand.

5.2.2. Study Design

The study involved purposeful or targeted sampling sometimes called judgement sampling, where respondents are selected because they have knowledge that is valuable to the research process (Bowling, 2005). The purpose of this sampling was to explore community pharmacists' diabetes knowledge and practice. The questionnaire (**Appendix 9**) was distributed and returned by hand to 125 community pharmacies located in diverse areas in Tripoli, which is Arabic speaking. Participants in purposeful samples are grouped into predefined criteria; i.e. they have particular characteristics that will allow the researcher to investigate the research topic as fully as possible. In this study the criteria used were that the targets should be community pharmacies located in Tripoli and employ a community pharmacist. This stage was also a recruiting stage for pharmacies to participate in the next stage (a randomised clinical trial). The study was approved by the Ethics Panel at the University of Bradford.

5.2.3. Justification of Methodology

The data relating to the aim of this chapter were collected using the methods discussed below.

5.2.4. Self-administered structured questionnaire

A questionnaire, as defined by Oppenheim (1992, p. 100), is ‘a set of questions including perhaps some open-ended ones, from more rigidly constructed scales or tests’. Siniscalco & Auriat (2005) define a questionnaire in more detail by stating that a questionnaire is a survey instrument used to collect data from individuals about themselves, with the questionnaire said to be standardised when each respondent is exposed to the same questions and the same system of coding responses.

The questionnaire adopted in the current study is a self-completion or administered structured questionnaire (SASQ). The self-administered structured questionnaire can be disseminated by hand (i.e. delivered at a person’s home or office), by post (i.e. via snail-mail), or otherwise via e-mail (Eliselen et al., 2005).

There are several advantages associated with the SASQ: it is a common method of covering a large geographically spread population relatively quickly and economically; the method is considered less of a social encounter than an interview method; there are fewer bias problems, which is useful for sensitive topics as there is more anonymity (Bowling, 2009); they are convenient since respondents can complete them at a time and place suitable for them; and they are relatively easy to administer and analyse. However, In contrast the method is unsuitable for respondents of poor literacy as well as for those with language difficulties, which do not exist in this case. There is generally a low response rate, although this can be improved. Furthermore, there is no opportunity to correct misunderstandings or to probe or to offer explanations or help, nor is there any control over the order in which questions are answered, and no check on incomplete responses (Oppenham, 1992).

Bowling (2009: 285) cites that "*there is some evidence that postal questionnaires leads to an underestimate of patients' health problems in comparison with personal interview techniques*" (Doll et al., 1991). Bowling agrees with the statement made by Doll by suggesting that "it may be that personal interviews can carry more social desirability bias and thus overestimate health problems" (Bowling et al., 1999; Bowling, 2005). Accordingly, Bowling highlights the belief that, if postal questionnaires underestimate health problems, interviews also overestimated them; I strongly agree with this statement the consequences of questionnaires that collecting data about general health problems but interview could provide ideas about the internal aspect of problem.

Centres for Disease Control and Prevention (CDCP, 2008) highlight that, when gathering data about knowledge, beliefs, attitudes and behaviours, questionnaires are helpful in providing information that is unique to individuals. As such, owing to the research being concerned with type II diabetes knowledge, attitudes and practices amongst community pharmacists, this methodology has been selected.

5.2.5. Structure of Questionnaire

Oppenheim (1992: 120–121) states that "*in reality, questioning people is more like trying to catch a particularly elusive fish, by casting different kinds of bait at different depths, without knowing what is going on beneath the surface! The function of a question in an interview schedule or questionnaire is to elicit a particular communication.*" This quotation means that the questionnaire is rather difficult to design. Owing to the frequency of their use in all contexts in the modern world, the structure of the questionnaire should have some robustness in order to collect valuable data. One of the factors centred on increasing the response rate is a covering letter; it is polite to attach this to the questionnaire. The covering letter contains basic information about the study and associated contact information.

A pilot questionnaire see **(Appendix 8)** was structured into four sections: section one designed to collect information about pharmacists and premises; section two concerned with the availability of oral hypoglycaemic and glucose and urine meters; section three sought to establish the workload and awareness of standard operating procedures; finally, section four aimed to achieve insight into family history and knowledge of diabetes. The diabetes knowledge test questions used in this section were taken from the Michigan Diabetes Research Training Centre (MDRTC). However, the main study questionnaire see **(Appendix 9)** was structured into three sections: section one contained information about people and geographical location of premises; section two concerned with the frequency of implementing standard operating procedures and the awareness of pharmacological management of glycaemic control in people with type II diabetes and also sought to understand reasons for not providing patient counselling; finally, section three aimed to achieve insight into family history and knowledge of diabetes

The components of the questionnaire (see **Appendix 9**) are described below.

Section one comprised questions about:

1. Pharmacy staff
    a. Level of education
    b. Programme studied (i.e. pharmacy, medicine or veterinarian etc.)
    c. Type of institution (i.e. whether graduate from university or college)
    d. Year of graduation
    e. Work experience
    f. Gender
    g. Diabetes specialized training
2. Pharmacy premises details
    a. Name of pharmacy
    b. Address
    c. Type of area (whether commercial or residential)

Section Two comprised questions about counselling practice. This section was divided into three parts: Standard Operating Procedures (SOPs); oral hypoglycaemic medicines (OHMs) recommendations adopted from SIGN; and reasons for not providing patient counselling.

1. Questions to understand the frequency of practice among participants. Items had been identified in two documents (Nursing and Midwifery

Council, 2007) and (WHO) but the questions were new not a direct adoption. The questions were:

a. How to use the medicine?
b. What the medicine is for?
c. Special storage instructions
d. When to use the medicine?
e. Side effects to expect
f. How the medicine is likely to affect their condition?
g. Offer patients information about medicines before the medicines are prescribed
h. Check that patients have any information they need about medicines when the medicines are dispensed
i. Discuss information about medicines with the patient rather than just presenting it

The standard operating procedures questions used to assess the practice of community pharmacist toward type II diabetes is general questions regarding the pharmacist practice but not specific to the diabetes management. The justification of using this kind of questions it simple and easy to understand. It is possibly avoiding ambiguity and bias.

Pharmacists were asked about SOPs which mainly concern safe dispensing practice. The pharmacist should engage both dispensing skills and clinical knowledge. The delivery of effective pharmaceutical care to patients requires pharmacists to practice in a way that uses their time effectively and reflects their responsibility and accountability.

1. The pharmacological management of diabetes means that the disease is treated with antidiabetic medicines, which could be oral hypoglycemic (OHMs) and/or insulin. The reason of asking questions about antidiabetic medicines was to understand the level of knowledge among community pharmacists. The questions ask pharmacists to rank recommendations about OHMs according to Scottish Intercollegiate Guidelines Network (SIGN) in order to assess community pharmacist's knowledge. The grade of recommendation relates to the strength of the evidence on which the recommendation is based. It does not reflect the clinical importance of the recommendation. Grade A means at least one meta-analysis, systematic review, or RCT rated as 1++, and directly applicable to the target population; or a body of evidence consisting principally of studies rated as 1+, directly applicable to the target population, and demonstrating overall consistency of results. Grade B means a body of evidence including studies rated as 2++, directly applicable to the target population, and demonstrating overall consistency of results; or extrapolated evidence from studies rated as 1++ or 1+. A tick means recommended as a best practice based on the clinical experience of the guideline development group. The statements in the questionnaire were adopted from SIGN and also recommended in the Libyan Diabetes Care Guideline (LDCG). The sets of recommendations adapted from SIGN were considered pharmacological questions.

2.

   a. Metformin should be considered as the first line oral treatment option for overweight patients with type II diabetes

b. Sulfonylureas should be considered as first line oral agents in patients who are not overweight, who are intolerant of, or have contraindications to metformin.
c. Pioglitazone can be added to metformin and sulfonylurea therapy, or substituted for either in cases of intolerance.
d. Pioglitazone should not be used in patients with heart failure
e. The risk of fracture should be considered in the long term care of female patients treated with pioglitazone
f. Patients prescribed pioglitazone should be made aware of the increased risk of peripheral oedema.

3. Questions about patient counselling: the reasons for not providing patient counselling adopted from Krska et al. (1995).
    a. Lack of pharmacist's time
    b. Lack of patient's interest
    c. Lack of patient's time
    d. Lack of support staff
    e. Lack of knowledge/training
    f. Lack of self-confidence
    g. Lack of pharmacist' interest
    h. Counselling not part of role

Section Three was an assessment of community pharmacists' diabetes knowledge. This section was divided into three parts: history of diabetes; background diabetes knowledge adopted from Michigan Diabetes Knowledge Test (MDKT) (Fitzgerald et al., 1998); practical diabetes knowledge adopted from Australian Diabetes Knowledge test (ADKT) (Eigenmann et al., 2011).

Therefore, the non- pharmacological diabetes questions were in this section. The non-pharmacological therapy consists of lifestyle modifications such as nutrition therapy, physical activity, avoidance of smoking and diabetic education (Meltzer et al., 1998). The set of questions adapting from MDKT and ADKT were about diet and exercising management of diabetes (non-pharmacological management awareness):

1. The good diabetic diet is:
   a) The way most Libyan people eat b) A healthy diet for most people
   c) Too high in carbohydrate for most people d) Too high in protein for most people
2. Which of the following is highest in carbohydrate?
   a) Baked chicken b) Edam chess
   c) Couscous d) Almond
3. Which of the following is highest in fat?
a) Low fat milk b) Orange juice
c) Sweet Corn d) Honey
4. Which of the following is a sugar free food?
   a) Any unsweetened food
   b) Any dietetic food (specially made for people with diabetes)
   c) Any food that says “sugar free” on the label
   d) Any food that has less than 20 calories per serving
5. What effect does unsweetened fruit juice have on blood glucose?
   a) Lowers it
   b) Raises it

c) Has no effect

6. Which should not be used to treat low blood glucose?

   a) 3 hard candies

   b) 1/2 cup orange juice

   c) 1 cup diet coca cola

   d) 1 cup skim milk

7. For a person in good glycaemic control, what effect does exercise have on blood glucose?

   a) Lowers it

   b) Raises it

   c) Has no effect

8. Eating foods lower in fat decreases your risk for:

   a) Nerve disease

   b) Kidney disease

   c) Heart disease

   d) ye disease

9. Which of the following statements about diabetes and diet is true?

   Please circle ONE answer only

   a) People with diabetes should eat a sugar free diet

   b) It is OK to eat fried take away food three times a week

   c) Red meat is a carbohydrate food

   d) A diet which is low in fat, high in fibre, low in added sugar is recommended for everyone with diabetes

   e) Unsure

10. How often should people with diabetes exercise or be physically active?

    Please circle ONE answer only

a) Most days of the week for at least 30 minutes

b) Once a week for at least 30 minutes

c) Once a month for one hour

d) At least every fortnight for two hours

e) Unsure

11. Why is doing regular exercise or being physically active good for your health?

    Please circle AS MANY as apply, or circle 'Unsure'

    a) It can help to control blood glucose levels

    b) It can lower blood pressure

    c) It can help to regulate a person's mood

    d) It can reduce the risk of skin cancer

    e) It can lower cholesterol levels

    f) Unsure

12. If a person with diabetes has a hypo (low blood glucose level) reaction, s/he should: Please circle ONE answer only

    a) Immediately take some insulin or diabetes tablets

    b) Rest and wait until s/he feels better

    c) Immediately have some sugary food or drink (e.g. jelly beans, soft drink)

    d) Drink some diet soft drink

    e) Unsure

1. Family history compromised the following items:

    a. Which kind of diabetes is suffered?

    b. Do you have a family history of diabetes?

    c. Who in your family has diabetes?

2. Background diabetes knowledge consisted of: fourteen items adopted from MDKT with slight changes in the types of food to fit availability in Libya or Libyan cuisine; and four questions generated from glucometer guidelines:
    a. MDKT questions
    b. Correct method of measuring blood glucose
    c. Normal range of blood glucose pre prandial
    d. Normal range of blood glucose after 2 hours from eating
    e. How to note your blood glucose measurements?
3. Eleven items adopted from the ADKT

The pilot **(Appendix 8)** and main questionnaire (**Appendix 9**) were similar in Section One and the MDKT questions. There was a difference in:

- Availability of OHMs (biguanides, sulfonylureas, benzoic acid & phenylanine derived, thiazolidiones, alphaglucosidase inhibitors, DDP-4 inhibitors 1 and GLP-1
- Availability of glucose meter and urine dipsticks. Caseload and workload.
- Reasons for pharmacy visits.

The reasons for this difference were:

- The availability of hypoglycaemic medicine and glucometers is not one of the study objectives the study concerned with clinical outcomes of glycaemic control (in terms of counselling and education).
- The current study does not concern the reasons why the clients visit the pharmacy.

5.2.6. Brief description of Michigan Diabetes Knowledge Test (MDKT) and Australian Diabetes Knowledge test (ADKT)

The knowledge question used were taken from both the Michigan Diabetes Research Training Centre (MDRTC) and the Australian National Consensus Position (ANCP) on Outcomes and Indicators for Diabetes Education (O&IDE), which identified knowledge and understanding as the outcomes most directly affected by diabetes education (Eigenmann& Colagiuri, 2011).

The Michigan Diabetes Knowledge Test (MDKT) comprises 23 knowledge test items; the first 14 items are used in the current study to assess pharmacists' knowledge (University of Michigan Health System, 2013). Fitzgerald et al (1998) stated that the knowledge diabetes test is reliable and valid, and is supported because the coefficient Alfa for the general diabetes test is ≥0.7. This suggests that the test is appropriate for a variety of settings. The test is also appropriate as a measure of general diabetes knowledge levels for researchers. It can be a useful method for group comparisons and for assessing knowledge over time. The usefulness of this test, as an outcome measure for educational interventions, remains to be fully determined. Al-Qazaz (2010) conducted a study to measure the reliability and validity of a Malaysian translated version of the MDKT. The findings of the validation study indicate that the Malaysian version was a reliable and valid measure of diabetes knowledge, and could be used in clinical and research practice. Importantly, MDKT data confirms its reliability and validity—even when translated into another language (Al-Qazaz, 2010).

The Australian National Consensus Position (ANCP) on Outcomes and Indicators for Diabetes Patient Education (O&IDPE) (Eigenmann & Colagiuri., 2007 , Colagiuri and Eigenmann, 2009) identified four patient-centred key outcome areas of knowledge and understanding, self-management, self-determination and psychological adjustment expressed in the order in which each area is most influenced by diabetes education. The ANCP developed their questionnaire by evaluating the available tools on their ability and suitability for measuring changes in the four key outcomes (Eigenmann et al., 2009).While three knowledge assessment tools were identified, none met all of the systematically derived quality appraisal criteria.

The first of the three tools, the diabetes knowledge test (DKT), was developed and validated in the mid-1980s by the Michigan Diabetes Research and Training Centre to address the need for a valid and reliable diabetes specific knowledge instrument that could be used by diabetes educators and researchers (Hess and Davis, 1983, Fitzgerald et al., 1998). In 1984, a series of three diabetes knowledge assessment scales (DKNA, DKNB and DKNC, each of 15 items) were developed and validated for the Australian environment (Dunn et al., 1984). None of the DKN scales had since been updated and they no longer reflected current Australian guidelines and standards of care (e.g. they referred to urine sugar testing which was no longer recommended) and, like the DKT, they contained many questions regarding insulin therapy, which did not fit the criteria for a generic tool that is applicable to all people with type I or II diabetes. The third identified validated knowledge questionnaire, the ADKnowl, was developed and tested in the UK (Speight and Bradley, 2001). It consists of 23-item sets with a total of 104 questions/ items which makes it a more comprehensive, thus a more onerous and resource intensive tool for application in a clinical setting, and hence did not meet the Australian criteria for a brief tool. Given the lack of an up-to-date, validated instrument, The ANCP aimed to develop, pilot and validate a generic, brief ADKQ capable of measuring knowledge change following a diabetes education intervention and which would be suitable for people with both type I and II diabetes.

The ADKQ includes separate questions for people not taking diabetes medication (12 items), people taking diabetes medication and/or insulin (two items) and additional items for people with type I diabetes only (total 15 items). The ADKQ is a brief, 15-item knowledge questionnaire with seven additional demographic questions added if required, taking between 5–15 minutes to complete – hence making it feasible to apply in a busy clinical setting. The readability, using the ‘Flesch Reading Ease’ test, was considered highly acceptable, hence making the tool applicable to people with a low literacy level. The importance of consumer input has been increasingly advocated by consumer and health care provider organisations.

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In the professional questionnaire both knowledge tests were used in order to assess diabetes background information and diabetes practice information. The first 14 items from the MDKT (Fitzgerald et al., 1998) were chosen and 11 items from the ADKT (Eigenmann et al., 2011). The selection of items was based on knowledge of five basic aspects of diabetes management (diet, blood glucose, feet, exercise, complications, and check-up managements) that were suitable to assess pharmacists' knowledge. A comparison was made between both tests (see Table 5.1).The table shows the differences around specific key managements of type II diabetes. The findings show that the MDKT asks about background information rather than practical concerns. Conversely, the ADKT address diabetes practice information. A view was taken that practical information provided a better understanding of professional or patient knowledge, and also it is easy to remember. However, background information may be it easier to forget and the context of background questions can be difficult to understand. Most studies using the MDKT for patients have found that patients with diabetes have poor knowledge (Al-Maskari et al., 2013, Al-Adsani et al., 2009, Odili et al., 2011). The validity of the MDKT cannot be questioned but it may present difficulties for both patients and professionals as a baseline assessment (rather than following specific training).

Table 5.1: Outline comparison between Michigan Diabetes Knowledge Test and Australian Diabetes Knowledge Test

MDKT	ADKT
Concerns background diabetes information	Concerns practical diabetes information
Somewhat complicated questions	Simple questions
Somewhat difficult to understand	Easy to understand
Valid and reliable when translated into other languages	Not translated into other languages
Questions do not provide reader with knowledge	Questions provide reader with diabetes knowledge
Different studies used	Is not used by other researchers
Old test	Recent test
There are no questions about diabetes health check-ups, diabetes medicine management and the definition of diabetes	There is questions about diabetes health check-ups, diabetes medicine management and the definition of diabetes

The detailed comparison between the MDKT & ADKT is provided in (**Appendix 10**). Both tests may be reliable and valid, but there are some differences in the way of asking questions. Concerning diet management, both define healthy diet but the ADKT adds that a healthy diet contain high fibre. Concerning blood glucose measurement management, the ADKT provides the respondent with the knowledge that HbA1c measures the average blood glucose over the past 2 to 3 months and tests the understanding of optimal blood glucose level. Concerning impact of infection on blood glucose the MDKT covers the consequences of infection. However, the ADKT covers self-management when you get cold or practical methods to manage the infection.

Concerning foot care management, the MDKT tests knowledge of foot care management and symptoms and the ADKT tests knowledge about symptoms of neuropathic complications. Concerning exercise management, the ADKT describes the importance of exercise precisely by testing the frequency of exercising and reason for exercising, while the MDKT asks about the impact of exercising when you have good blood glucose control. Concerning blood glucose management, the ADKT highlights the reason for monitoring blood glucose, but the MDKT highlights the best method of blood glucose measurement. MDKT tests the respondents understanding about diabetes complications. However, the ADKT highlights the benefit of good diabetes management on patients' health and address the complications of diabetes at the same time. Concerning hypoglycaemic management, the MDKT defines which sweet drink should be avoided whilst the ADKT asks how to manage hypoglycaemia effectively and clarifies which sugary drink is recommended. Concerning check-up management, in the MDKT there are no questions about the importance of check-ups but the ADKT shows concern for the importance of health check-up for eyes, feet and kidney. Concerning diabetes medication management, there are no questions in the MDKT, nor any questions about the definition of diabetes.

5.2.7. Study Hypotheses

The hypothesis below were tested in the pilot questionnaire (with a small sample size) and re-tested in the analysis of the main questionnaire.

- More years of experience would be associated with higher MDKT scores.
- More years of experience would be associated with greater adherence to SOPs.

5.2.8. Statistical Analysis

The data was analysed using Statistical Package for Social Sciences (SPSS) and Excel. Descriptive statistics were used for demographic characteristics. Bar charts used to highlight frequency of SOPs, reasons for not providing patient counselling and categories of type II diabetes knowledge test. Regression analysis was used to test the association between acquiring high scores of MDKT and more years' experience.

Questions about SOPs had the options “always”, “frequently”, “sometimes”, “rarely” “never”. The “always” and “frequently” option was considered as good practice and other options were considered as negative practice. One score was given to each “always” and “frequently” option and the practice score was calculated by adding the points for each “always” and “frequently” answer. The total score for practice was classified into “positive practice” for score ranging (5.5–11) and “negative practice” for (0–5). This kind of analysis was adopted from Al-Maskari et al. (2013) and Shrestha et al. (2015).

5.3. Results of Community Pharmacists Their Knowledge and Practice toward Type II Diabetes

The study was carried out in Tripoli, Libya, in which there are 426 community pharmacies (WHO, 2007). One hundred and twenty five copies of the questionnaire were delivered by hand; of these, one hundred and eight were returned (86% response rate); seventeen (13%) were not returned. This is the first stage of a wider study and was considered an exploration to enable shaping of the training for community pharmacists for the remainder of the project.

5.3.1. Response rate

The piloted sample and main sample participants are completely different to avoid study bias. For the piloting stage, a total of 53 copies of the self-completion questionnaire (**Appendix 8**) (see flow chart **Figure 5.1**) were distributed by hand. There were 30 Arabic translated versions (distributed on October 1, 2012) from which 8 refused participation for different reasons: 5 participants stated a lack of time, whilst 3 neglected to fill in the questionnaire and were deemed not interested in the study. Furthermore, 23 copies of the English version of the questionnaire were distributed by hand on December 18, 2012 with all collected (Elhatab, 2013).

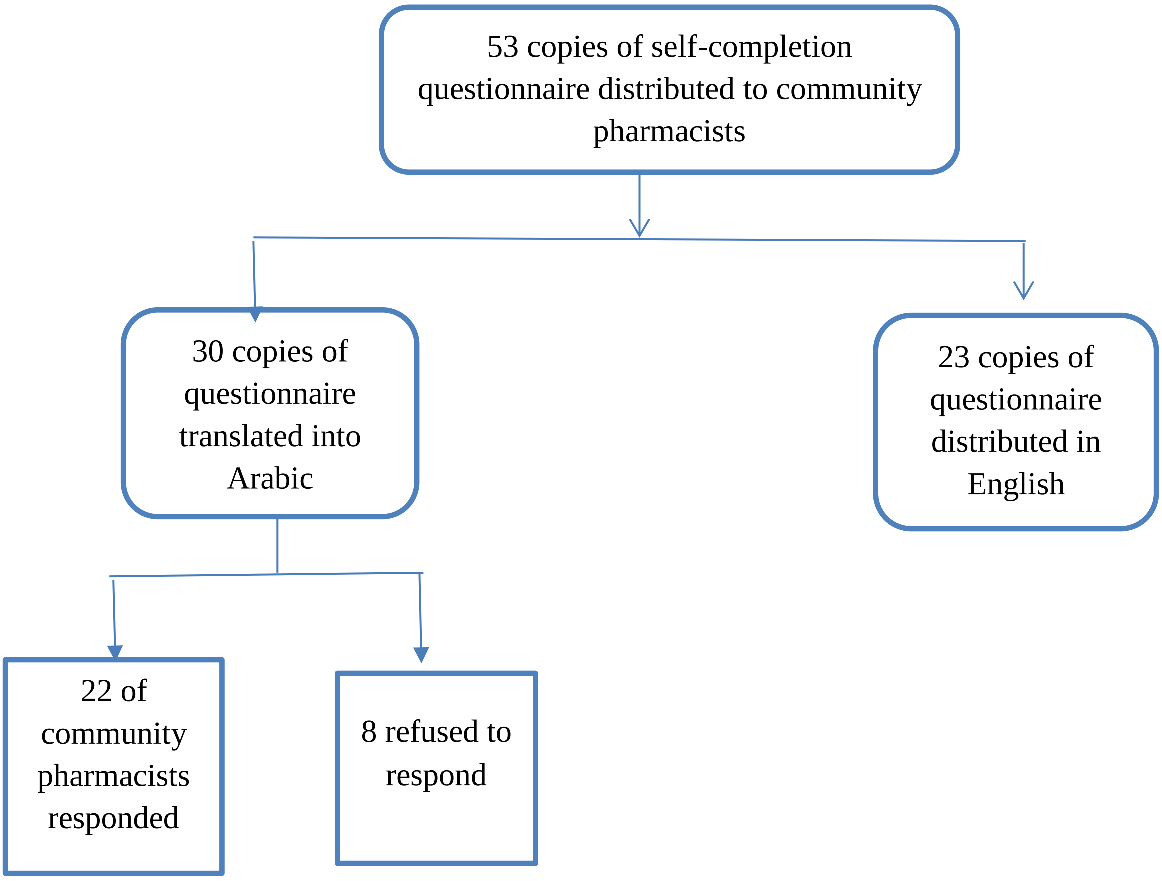

Figure 5.1 : Flow chart showing distribution of pilot self-completion questionnaire

For the main type II diabetes knowledge and practice questionnaire a total of 125 copies of the final self-completion questionnaire (**Appendix 9**) were distributed by hand in August 2014; of these, one hundred and eight were returned a total of 17 refused participation for different reasons; 10 participants stated a lack of time, whilst 7 neglected to fill in the questionnaire and were not interested in the study (see flow chart **Figure 5.2**).

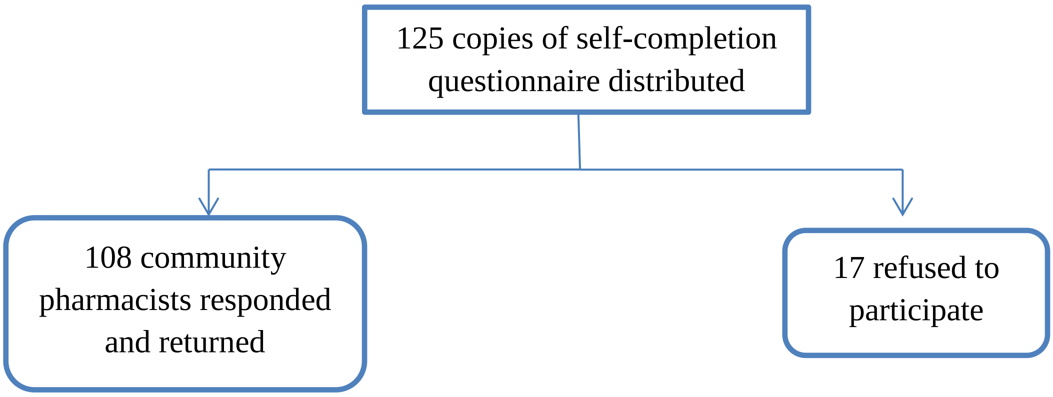

Figure 5.2: flow chart of main study

5.3.2. Respondents' Demographic and Characteristics

Data was gathered from 108 copies of the main self-completion questionnaires (see **Appendix 9**) distributed to 30 areas located in Tripoli. **Table 5.2** shows the demographic characteristics of community pharmacists in Tripoli, Libya. Nearly three quarters were qualified with a bachelor degree (n=74/100, 74%), in almost all cases this was pharmacy (n=93/98, 95%) and studied at university (n=90/100, 83%); there were equal numbers of males (n=55/108, 50%) and females (n =53/108, 49%). The mean (±sd) years of experience as a community pharmacist were 6 (±5.13). Over three quarters of respondents did not have diabetes special training (84/107, 79%). Just over half of the community pharmacies were located in commercial areas (n=63/108, 58%).

Table 5.3 indicates the personal history of diabetes among participants. Most of the pharmacists did not have diabetes (103/108, 95%). However, more than three quarter of respondents had a family history of diabetes (81/108, 75%) and for half of participants this was close relatives with their parents having diabetes (54/108, 51%).

Table 5.2: Demographic characteristics of respondents

Parameter	Number	Percent
Total number	108	100%
Academic Qualification		
Higher diploma	13/100	13%
Bachelor	74/100	74%
MSc	13/100	13%
Which faculty graduated from:		
Facility of Pharmacy	93/98	95%
Facility of Medicine	5/98	5%
Institution		
University	90/100	83%
College	10/100	9%
Years of graduation		
1981-1990	3/101	3%
1991-2000	4/101	4%
2001-2010	76/101	75%
2011-2013	18/101	18%
Years of profession as community pharmacy		
1-10	94/101	93%
11-20	4/101	4%
21-30	2/101	2%
31-40	1/101	1%

Continue…… Table 5.2

Parameter	Number	Percent
Gender	55/108	51%
Male	53/108	49%
Female		
Special diabetes training		
Yes	23/107	22%
No	84/107	79%
Area location		
Residential	45/108	42%
Commercial	63/108	58%
Number of participants provided contact details		
Yes	55/108	50%
No	53/108	49%

Table 5.3: Personal history of diabetes

Parameter	Number	Percent
Personal diabetes		
Type I	4/108	4%
Type II	1/108	1%
No	103/108	95%
Family history of diabetes		
Yes	81/108	75%
No	27/108	25%
Who have diabetes in your family?		
Father or mother	54/108	50%
Aunt or uncle	14/108	13%
Brother or sister	4/108	4%
Grandparents	11/108	10%

5.3.3. Frequency of implementing standard operating procedures (SOPs)

Table 5.4 shows that the community pharmacist generally had negative practice (60/103, 58%). **Table 5.5** and **Chart 5.1** show that the most common practices that pharmacists always performed were to give information about: how to use the medicine (n=80/103, 79%); what is the medicine for (n=61/101, 61%); when to use medicines (n=54/98, 56%); and special storage instructions (n=47/99, 48%). On the other hand, when comparing with other SOPs, it can be seen that the highest percentages of SOPs that are never performed include: discuss information on medicines with the patient rather than just presenting (n=22/101, 22%); offer patients information about medicines before the medicines are prescribed (16/100 16%); and check that patients have any information they wish about medicines when the medicines are dispensed (n=15/99, 15%).

Kruskal Wallis Test results (see **Table 5.6)** shows there is no difference between years of experience and greater adherence to SOPs, the prior hypothesis was rejected. With respect to offering patients information there is a trend (p=0.06) towards an associated with years of experience.

Table 5.4: Positive and negative practice toward type II diabetes

Practice scores	Frequency	Percent
5.5-11(positive Practice)	43/103	42%
0-5 (Negative Practice)	60/103	58%
Total	108	100

Table 5.5: Frequency of implementing standard operating procedures (SOPs)

Items of SOPs	Always N (%)	Frequently N (%)	Sometimes N (%)	Rarely N (%)	Never N (%)
How to use the medicine	80/103 79%	19/103 18%	2/103 2%	2/103 2%	0/103 0%
What is the medicine for?	61/101 61%	30/101 29%	7/101 7%	3/101 3%	0/101 0%
Special storage instructions	47/99 48%	22/99 22%	18/99 17%	7/99 7%	5/99 5%
When to use medicines	54/98 56%	19/98 20%	17/98 17%	5/98 5%	3/98 3%
Food/drinks to avoid	40/100 39%	20/100 20%	25/100 25%	10/100 10%	5/100 5%
Special instructions	35/100 35%	23/100 23%	21/100 21%	15/100 15%	6/100 6%

Side effects to expect	26/97 27%	24/97 25%	28/97 29%	14/97 15%	5/97 5%
How the medicine is likely to affect their condition (that is, benefits)	27/100 27%	25/100 25%	31/100 31%	9/100 9%	8/100 8%
Offer patients information about medicines before the medicines are prescribed	17/100 17%	9/100 9%	35/100 35%	23/100 23%	16/100 16%
Check that patients have any information they wish about medicines when the medicines are dispensed	15/99 15%	14/99 14%	28/99 28%	27/99 28%	15/99 15%
Discuss information on medicines with the patient rather than just presenting it	12/101 12%	12/101 12%	29/101 29%	26/101 26%	22/101 22%

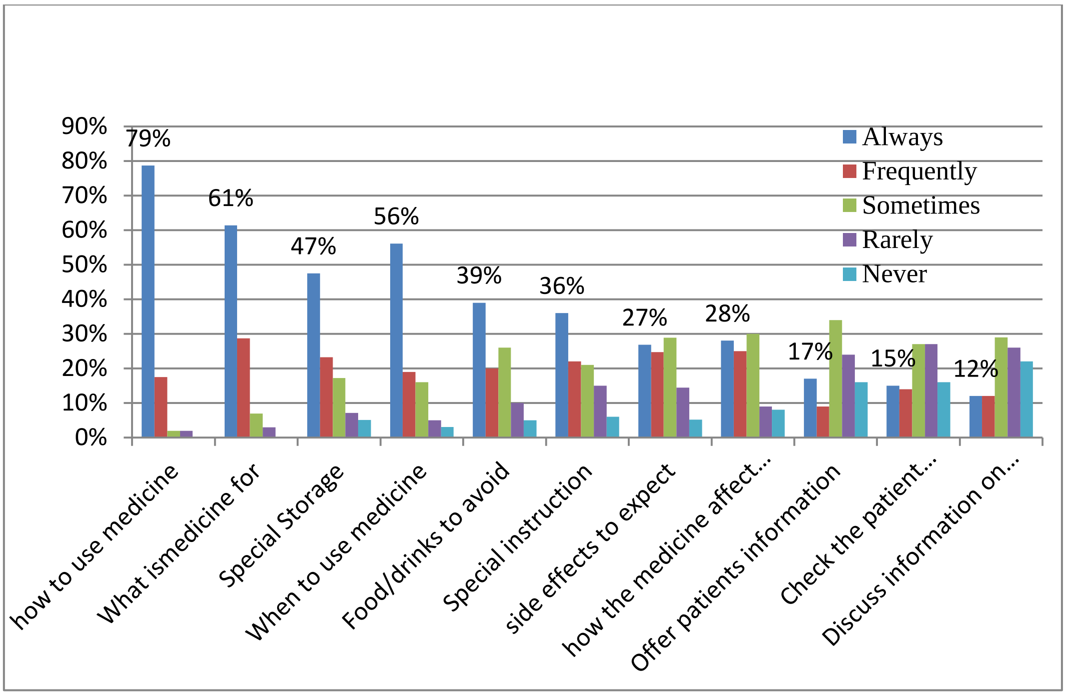

Chart 5.1: Frequency of implementing standard operating procedures (SOP)

Table 5.6: Kruskal Wallis Test to test hypothesis that more years of experience is associated with greater adherence to SOPs

Items of SOPs	Chi-Square	Df	Asymp. Sig.
How to use the medicine	2.862	3	0.413
What is medicine for?	2.457	3	0.483
Special Storage	4.332	3	0.228
When to use the medicine	1.703	2	0.427
Food/drinks to avoid	4.764	3	0.190
Special instruction	3.700	3	0.296
Side effects to expect	3.327	3	0.344
How the medicine is likely to affect your condition	3.977	3	0.264
Offer patients information	7.286	3	0.063
Check that patient have information they need about the medicine	3.891	3	0.274
Discuss information on medicine	5.055	3	0.168

5.3.4. Reasons for not providing patient counselling

Patient counselling is a key competency element of the pharmaceutical care process (NBPS, 2015). In practice, it ranges from simply stating the dosage of a drug as it is handed over to the client, through counter prescribing for common ailments, to giving advice with regard to lifestyle and health promotion issues, like smoking cessation, cholesterol testing and contraception (Pilnick, 2003). In Libya, there is a lack of patient counselling strategy and understanding what hiders patient counselling is important.

As shown in **Table 5.7** the lack of support staff (4.03 ±1.17) was rated as a very important reason for counselling not being given. Less important reasons were counselling not being part of role (1.80 ±0.97), lack of knowledge/training (1.81 ±1.17), lack of pharmacists interest (1.84 ±1.02), lack of self-confidence (1.92 ±1.01), lack of patients interest (2.13 ±1.23), lack of pharmacists time (2.32 ±1.40) and lack of patients time (2.50 ±1.13).

Table 5.7: Reasons for counselling not being provided

Reasons	Number of pharmacists	Rating (Mean ±SD, scale 1 very low to 5 very high)
Lack of pharmacists time	101	2.32 ±1.40
Lack of patients interest	101	2.13 ±1.23
Lack of patients time	101	2.50 ±1.13
Lack of support staff	100	4.03 ±1.17
Lack of knowledge/training	101	1.81 ±1.17
Lack of self confidence	100	1.92 ±1.01
Lack of pharmacists interest	101	1.84 ±1.02
Counselling not part of role	101	1.80 ±0.97
Total	108	

5.3.5. Awareness of oral hypoglycaemic medicine recommendations

Table 5.8 assesses pharmacist awareness regarding type II diabetes oral hypoglycaemic agent recommendations, which were adopted from SIGN. The items used from SIGN 116 are also recommended in Libyan Diabetes Care Guidelines (LDCG) but with slight differences. Nearly three quarters of participants correctly answered with grade A that metformin is first line therapy (74/100, 74%) and 45% (43/96) answered correctly that pioglitazone should not be used in patients with heart failure. While just one quarter (23/98, 24%) answered correctly that the risk of fracture should be considered in the long term care of female patients treated with pioglitazone. A low number of pharmacists were aware that patients prescribed pioglitazone should be made aware of the increased risk of peripheral oedema (15/98, 15%).

5.3.6. Pharmacists' Diabetes Knowledge Test

The DKT used comprised 29 items; the statistics show that the community pharmacist average scores was 21/29 (±3.16) with a range of 12–26, meaning they generally had good diabetes knowledge. **Table 5.9** & **Chart 5.2** show the items of the diabetes knowledge test characterised into four categories (with average scores and correct percentage): measuring blood glucose (5.03±1.19, 72%), lifestyle management (8.08±1.61, 67%), foot care and infection management (4.99±1.10, 83%) and diabetes general management (2.86±0.93, 72%). Table 5.10 shows that the average scores in each tool of diabetes knowledge test. The ADKT average scores were 8.9/11±1.56 and average scores for MDKT were 9.3/14±2.17 and the items of testing pharmacist's knowledge toward measuring blood glucose 2.7/4±1.00.

Table 5.8: Responses of Scottish Intercollegiate Guidelines Network Recommendation

Items	Grade A	Grade B	✓ Recommended best practice
Metformin should be considered as first line oral treatment option for overweight patients with type II diabetes	74/100 74%	14/100 14%	12/100 12%
Sulfonylureas should be considered as first line oral agents in patients who are not overweight, who are intolerant of, or have contraindications to, metformin	24/97 25%	43/97 44%	30/97 31%
Pioglitazone can be added to metformin and sulfonylurea therapy, or substituted for either in cases of intolerance.	33/96 34%	33/96 34%	30/96 31%
Pioglitazone should not use in patients with heart failure	43//96 45%	21/96 22%	32/96 33%
The risk of fracture should be considered in the long term care of female patients treated with pioglitazone.	46/98 47%	23/98 24%	29/98 30%
Patients prescribed pioglitazone should be made aware of the increased risk of peripheral oedema.	66/98 67%	17/98 17%	15/98 15%

Table 5.9: The responses to the diabetes knowledge test

Categories of DKT	No of items	Mean (SD)	Correct answers (%)
Measuring blood glucose	7	5.07(±1.22)	72%
Lifestyle management (diet and exercise)	12	8.08(±1.61)	67%
Foot care and infection management	6	4.99(±1.10)	83%
Diabetes general management	4	2.86(±0.93)	72%
Total knowledge score	29	21.0(3.16)	72%

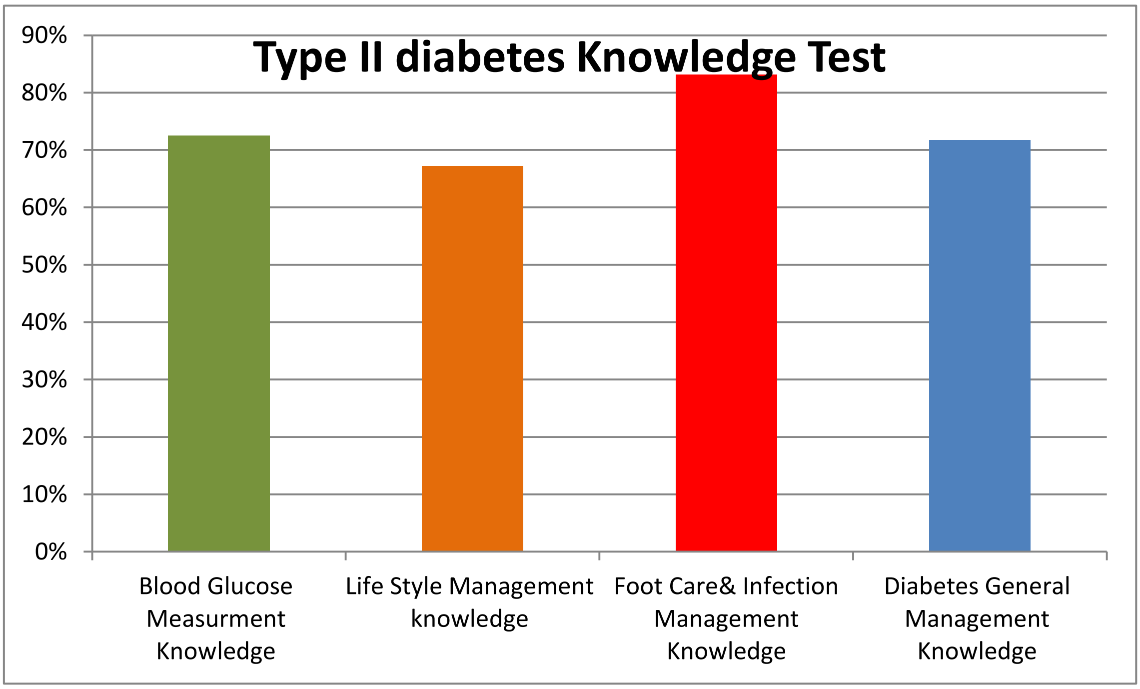

Chart 5.2: The results of four categories of pharmacist's diabetes knowledge test

Table 5.10: The average scores in the ADKT, MDKT and blood glucose measurement test

Parameters	ADKT	MDKT	Blood glucose measurement test
Mean (± sd)	8.9±1.56	9.3±2.17	2.7±1.00
Number of questions	11	14	4
Total of respondents: 108			

A prior hypothesis was that more years' experience would be associated with higher DKT scores. In the pilot sample an association was seen. However, the results of regression analysis in this larger sample showed no relationship between years of experience and acquiring high DKT scores ($b= 0.03$; $p=0.56$). Therefore, the null hypothesis was accepted that there is no difference between pharmacist's diabetes knowledge and years of experience practicing as community pharmacist (in the current sample).

5.4. Discussion

Pharmacists are part of a multidisciplinary team. This team normally consists of pharmacist, physician, nurse, technician, nutritionist, and other health care professions. Intensive diabetes education and care supervision can progress patient outcomes, glycaemic control and improve standard of life in patients (McMurray et al., 2002). Our study shows that the community pharmacists have good knowledge about type II diabetes care. The response rate was very good at 86.4%. As reported by Elerby et al., (1993) and Rosenbloom (2000), attitude surveys suggest 32% of pharmacists participate in pharmacy practice research, but actual involvement rates were as low as 6%. For the diabetes knowledge test, a previous study found that the participants' mean knowledge score was 10.67/20 (Shrestha et al., 2015); while the mean score in the current study was 21/29 (±3.16). 75% of participants in the current study had a family history of diabetes, which could be a factor in pharmacist's good knowledge about type II diabetes management. 83% of participants scored higher in the awareness of foot care and infection management it seems that most pharmacists were aware that damage to the nerves of the foot can mean small nicks and cuts aren't noticed and this, in combination with poor circulation, can lead to foot ulcers. However, the knowledge about lifestyle management (diet and exercise) was the lowest at 67%, which is the main focus in the current study regarding non-pharmacological management of type II diabetes. This is the reason to do training in next stage of the study to make sure that the community pharmacists are able to provide patient participants with the recommended information.

The study shows that the diabetes knowledge is better than in the study conducted by Bisheya et al (2011). The questions used to measure awareness among community pharmacists were the Michigan Diabetes Knowledge Test (MDKT) and the Australian Diabetes Knowledge Test (ADKT). Average scores in the ADKT were better than the MDKT that is because the MDKT asks background questions (which are easy to forget) rather than practical ones. I used the concept of standard operating procedures (SOPs), which includes all the written protocols and procedures in place within a pharmacy. They state the way that the pharmacy expects tasks to be carried out to ensure provision of a quality service. They include, for example, the questions that must be asked of a patient so that his or her needs can be correctly identified and appropriate action taken (Langley & Belcher, 2012). A commonly encountered strategy for improving patient safety is the standardisation of healthcare practice, often by developing and implementing standardised procedures (in the form of guidelines, protocols and standard operating procedures (SOPs) (Harrison & Smith, 2004). In principle, procedures provide assurance by holding healthcare staff to a minimum standard of practice and controlling aspects of their work that may create patient safety hazards (Berwick, 1991; Smith, 2009). Some studies found that the implementation of SOPs has had a more limited effect on working practices than anticipated (Pittet et al., 2000; Smith et al., 2006; Walker et al., 2001; Watson et al., 2006). Our results are consistent with previous studies around SOPs, which indicated that community pharmacist had limited adherence to some (recommended) tasks (categorised in the current study as a negative practice). Thomas et al (2017) suggested that such findings have led researchers to examine the relationship between procedures and practice in healthcare. Reason et al (1998) and Dekker (2003) noted that strict adherence to inflexible procedures can make a task inefficient, or even unachievable, in practice.

The relationship between procedures and practice can be understood in terms of organisational 'resilience' that is, the ability of an organisation or its members to maintain effective and efficient work in the face of a dynamic environment that is characterised by discontinuities in care, hazards, trade-offs and multiple goals (Cook et al., 2000; Jeffcott et al., 2009). According to the notion of resilience, staff may adapt their work activity in order to achieve task goals under the prevailing circumstances, thus creating a divergence between 'work as imagined' (as represented by the formal procedures) and 'work as done' (as represented by actual practice at a given time or in a given location) (Dekker, 2003; Hollnage et al., 2007; Hollnagel, 2015). Hence, the effect of implementing procedures is determined by the relationship between these two aspects of work.

There are some limitations and difficulties faced in the study. Despite the fact that self-administered questionnaires are often the only financially viable option when collecting information from large, geographically dispersed populations, it has been shown that this method of data collection has various disadvantages (Smeeth et al., 2001, Edwards et al., 2002). The questionnaire was distributed by hand due to the unstable situation in Libya. The method of collecting data is stressful and time was limited. Moreover, other difficulties were faced in that the collection of data took a prolonged time because the data was returned via air to the UK. Is not easy delivering questionnaires by hand; it is an old method; however, the situation in Libya is difficult and so there was no choice.

5.5. Conclusion

This study identified the current diabetes knowledge and practice of community pharmacists in Tripoli, Libya. In general, our results suggest that community pharmacists had good knowledge about diabetes, which could be a foundation for more clinical practice. Basic provision of information for patients appeared to be good; however, there were opportunities to enhance the level of care provided.

5.6. Chapter summary

The survey highlights the knowledge and practice toward type II diabetes among community pharmacists in Tripoli, Libya. Reliable tools were used to measure diabetes knowledge: Michigan Diabetes Knowledge Test (MDKT) (Fitzgerald et al., 1998) and Australian Diabetes Knowledge Test (ADKT) (Eigenmann et al., 2011). A comparison between MDKT and ADKT showed that the tested background knowledge while the measured practical diabetes knowledge. For this reason, both tests were used to provide a full picture of community pharmacists' diabetes knowledge. This knowledge will be employed for the next stage of study, a randomised controlled trail. The counselling practice (Nursing and Midwifery Council, 2007) identified in our study suggests that the community pharmacist require training to enhance their counselling practices. This data agrees with a study completed in Saudi Arabia, which also observed pharmacist counselling practice and found that there were deficiencies in appropriate dispensing practices and medication counselling in community pharmacies (Alaqeel and Abanmy, 2015). The authors recommended that policy makers, stakeholders, and researchers should collaborate to design interventions to improve the current dispensing practices in community pharmacies (Alaqeel and Abanmy, 2015).

In Chapter Six the training stage will be described and evaluated.

Enhancing community pharmacists knowledge (training stage)

This chapter explains the importance of pharmacist education to enhance the role of pharmacists in type II diabetes disease management. This chapter is divided into six sections. The introduction **Section 6.1** highlights the main aspects of pharmacist training. The methods and study design are outlined in **Section 6.2.** Statistical results are provided in **Section 6.3.** The discussion is in **Section 6.4** and the conclusion in Section 6.5. A chapter summary is provided in **Section 6.6.**

6.1. Background of the main aspects of pharmacist training

The aim of the current study is to develop the role of community pharmacists in type II diabetes management. Enhancement of community pharmacists' diabetes knowledge and practice is needed to improve counselling skills for patients with type II diabetes. Pharmacists are highly accessible to chronically ill patients such as those with diabetes, especially when the disease becomes controlled and the patient only needs to visit a pharmacy to have their prescription refilled. Pharmacists' knowledge and attitudes toward diabetes could significantly influence patient outcomes. Given the prevailing concept of a team approach toward diabetes care, only when all health care providers share the same high level of knowledge and positive attitudes could the quality of patient care be ensured (Chen et al., 2004).

Pharmaceutical care has significantly reduced the occurrence of drug-related problems and fulfilled the desired outcomes of drug therapy in other diseases and conditions such as anticoagulation, hyperlipidaemia, and asthma (Garabedian-Ruffalo et al., 1985, Pauley et al., 1995). Studies have also shown that pharmacists' participation in the care of poorly controlled patients with type II diabetes resulted in better outcomes (Davidson et al., 2000, Mehuys et al., 2011, Poolsup et al., 2013). However, even in developed countries like the USA, pharmacists participating in diabetic care are still not required to be Certified Diabetes Educators (CDEs); and applying the practice of pharmaceutical care to CDE certification could strengthen the team approach toward diabetes care and therefore warrants careful consideration (Chen et al., 2004).

The practice of diabetes care has dramatically changed during the past two decades. Knowledge regarding diabetes pathophysiology has quickly accumulated and has led to the development of new medications. In addition to knowledge updates, the attitudes of health care professionals toward current concepts in diabetes care are even more critical. The core philosophy of modern diabetes care puts emphasis on patient autonomy and optimal utilization of health care professionals' from different specialties. Research evidence derived from clinical, economic, and humanistic outcomes also strongly supports the importance of patient autonomy and a team approach to diabetes care. To address the needs in clinical practice in the USA, a continuing education (CE) programme and a Certificated Diabetic Educator (CDE) designation were created to help pharmacists catch up with the developments in diabetes care (Chen et al., 2004).

The efficacy of a diabetes CE programme should be systematically evaluated to ensure the fulfilment of its goal of bridging the gap between current practice and the most up-to-date evidence-based guidelines. Using short-term indicators to evaluate the impact of a CE programme could be an essential part of establishing integrated diabetes care. Assessing changes in knowledge provides direct, initial understanding of the impact of a CE programme. However, improvements in knowledge often cannot predict the improvements in practice (Chen et al., 2004). The theory of reasoned action states that people intend to perform behaviour, such as encouraging patients to monitor blood glucose levels, only when they evaluate it positively (Ajzen and Fishbein, 1977). Knowledge as well as health care providers' attitudes will influence their clinical practice and patient outcomes. Measuring changes in attitudes toward diabetes provides better insight into the true influences of a CE programme (Sharp and Lipsky, 1999). Continuing professional development (CPD) is a framework for, or approach to, lifelong learning and is being discussed as a potential model for pharmacists in the United States. CPD is not a replacement for continuing education (CE), as quality-assured CE is an essential component of CPD (Rouse, 2004).

6.2. Methods

The training of community pharmacists was carried out after randomisation at the areas level or geographical classification of areas (see **Appendix 24**). There were 40 pharmacies in the clinical trial, which were split into 18 control and 22 intervention locations. The education materials (see **Appendix 12**) were provided to intervention community pharmacists only. The education material was adapted from a website called diabetescare.net and permission requested from David Day the web content manger. The material is provided on the website as education for type II diabetes patients. The study protocol was provided to both control and intervention pharmacists. The education materials were sent by email to some places and hand delivered to others, because of difficulty with internet connections. If intervention pharmacists had weak knowledge in any area, then they were sent a specific communication to correct and enhance that knowledge.

Method of training:

The twenty two intervention community pharmacists had been assessed with a diabetes knowledge test combining the Australian diabetes test and the Michigan diabetes test (Eigenmann et al., 2011, Fitzgerald et al., 1998). The reliability and validity of both tests is known. The investigator assessed pharmacists' knowledge then sent education materials to the participants (see **Appendix 11**). The sheets highlighted areas of weakness for each respondent to improve their knowledge in specific areas. The documents were sent by email to 10 participants and to 11 by hand. Then, the participants were contacted by telephone to understand how they were doing and to explain the study protocol. After three months the community pharmacists were contacted by email and telephone and requested to take the test again to re-assess their knowledge (see **Appendix 12**). The study protocol was provided to both control and intervention pharmacists. Eighteen community pharmacists in the control arm were trained just for the study protocol. The study protocol was explained via telephone and Skype contact by asking the community pharmacist to:

- Greet the patient;
- Provide the patient with a glucometer;
- Ask the patient to record the FPG on three consecutive days by recording the measurements on the FPG recording sheet (**Appendix 28**);

- Provide patients with three printed sheets of questionnaires (**Appendices, 18, 19 and 20**). Ask the patient to fill the entire questionnaire and after three days return both the FPG record sheet and questionnaire sheets.
- After six months of study. The patients were contacted by the phone to attend the pharmacy. To provide the patients with FPG record sheet and three sheets of questionnaire.

Rationale for educational materials

The training educational materials (**Appendix 12**) cover the components of the intervention:

- Education about type II diabetes and it complications
- Education about the correct use of oral hypoglycaemic agents (timing in relation to food);
- Healthy lifestyle education (diet, physical exercise and smoking cessation); and
- Reminders about annual eye and foot examinations

Defining type II diabetes along with complications was described in section one & two. The information regarding oral hypoglycaemic medicines was highlighted in section two and section five, the healthy lifestyle information is in section two and section four. Reminders regarding annual health checks were described in section two. Other information about hypoglycaemic management was highlighted in section two (Rule of 15) and the diabetes emergency plan was described in section three.

In the educational materials health literacy is not described in context. However, the investigator used plain language in the printed educational materials (**Appendix 25, 26**) that were handed to patients in the intervention study (see **Chapter 7**).

6.2.1. Study design

The study was designed as a randomised clinical trial, the community pharmacies were randomised before the start of the training stage. Random sampling justify that each individual have same opportunity to include in the study. The flow chart (**Figure 6.1**) shows the distribution of community pharmacies in the training step.

6.2.2. Statistical analysis

Knowledge before and after training was analysed using SPSS 22. The descriptive statistics generated were: frequency, standard division, and range of scores. The detailed analysis plan split the twenty nine questions into four sub-scales: Measuring Blood Glucose (MBG), Lifestyle Management (LSM), Foot Care and Infection Management (FCIM) and General Diabetes Management. The sub-scales contained: seven items for MBG, twelve items for LSM, five items for FCIM and five items for (GDM). Then each sub-scale was compared visually before and after training by using multiple bar charts paired samples t-test compared before and after performance on each sub-scale and the average score for the whole questionnaire

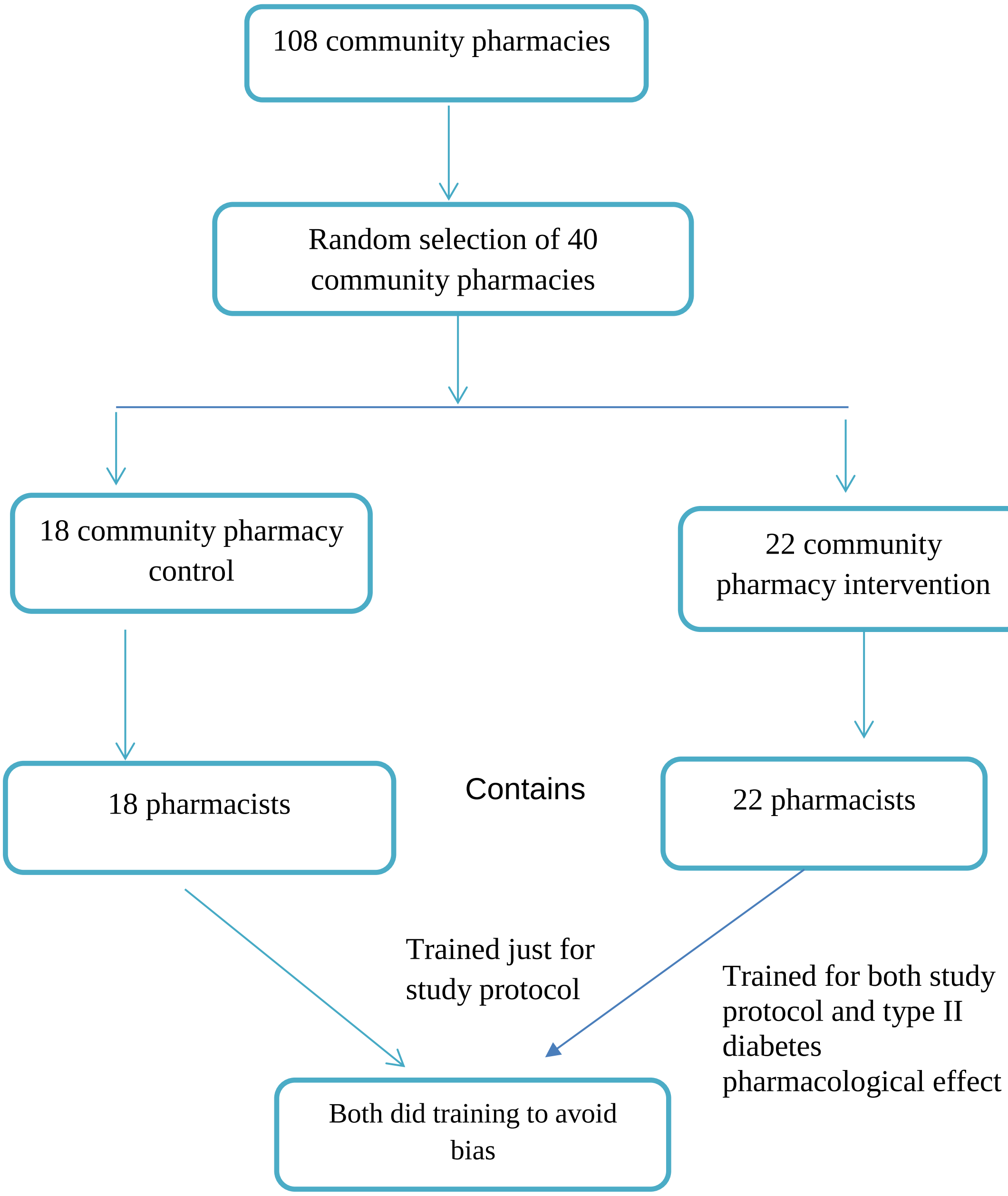

Figure 6.1: Flow Chart of training community pharmacies

6.3. Statistical results

6.3.1. Demographic characteristics of respondents

Table 6.1 describes the participants' demographic profile in the training stage. There were 11 (61%) female pharmacists in the control group and 9 (41%) in the intervention group. In the control group 6 (33%) pharmacists had received special training about diabetes against 2 (9%) in the intervention group. Most participants did not have personal experience of diabetes, except for one in the intervention group. In both control and intervention groups the prevalence of diabetes family history was high (18, 100% vs 21, 95%).

Table 6.1: Demographic characteristics in the training stage

Items	Control	Intervention
Total	18	22
Gender		
Male	7 (39%)	13 (59%)
Female	11 (61%)	9 (41%)
Special Diabetes Training		
Yes	6 (33%)	2 (9%)
No	12 (67%)	20 (91%)
Location		
Commercial	13 (72%)	8 (37%)
Residential	5 (28%)	14 (64%)
History of diabetes		
Yes	0 (0%)	1 (5%)
No	18 (100%)	21 (95%)
Family history of diabetes		
Yes	14 (78%)	13 (59%)
No	4 (22%)	9 (41%)

6.3.2. Diabetes knowledge test

The diabetes knowledge test was used to assess the intervention group before and after training to measure any improvement in diabetes knowledge among participants. There were 29 questions about type II diabetes. The average knowledge score before training in the control group was 19.4/29±3.14 vs 21.6/29±3.09 intervention to facilitate comparison, before and after results for the four sub-scales are shown in **Charts 6.1** to **6.4**

Chart 6.1 shows that before training the number of correct responses were lowest for understanding the HbA1c test (12, 55%). **Chart 6.2** shows an improvement after training in knowledge about HbA1c (16, 73%) and improvement in knowledge about: correct glucometer use; the normal range of blood glucose (BG); and the normal range of BG after 2 hours of meal. Reasons for testing blood glucose were well understood both before and after training (22, 100%).

Chart 6.2 shows the level of awareness about lifestyle management before training. The worst knowledge revealed is the awareness of sugar free food answered correctly by 6 out of 22 (27%) but after training the number of respondents answering correctly increased to 20 (91%) .Lower levels of knowledge were also apparent before training for the question asks: Which should not be used to treat low blood glucose (8, 36%), the effect of unsweetened juice on hypoglycaemia (10, 45%), and the kinds of food high in fat (10, 45%).

The third sub-scale (diabetes foot care and infection management) is presented in **Chart 6.3**. This shows the worst knowledge around the impact of infection or influenza on blood glucose (15/22, 68%) but this is improved after training (20/22, 91%).

General diabetes knowledge management is presented in **Charts 6.4**. . Before training the worst knowledge is seen for a question about the recommended frequency of medical check-ups for eyes, nerve and kidney function. The correct answer (once a year) was given by only 9 out of 22 (41%) but this improved after training to 18 (82%).

Table 6.2 shows the improved scores before and after training for the intervention pharmacists. The data shows that there was a significant enhancement in the diabetes knowledge test around measuring diabetes knowledge and lifestyle management (P>0.001).

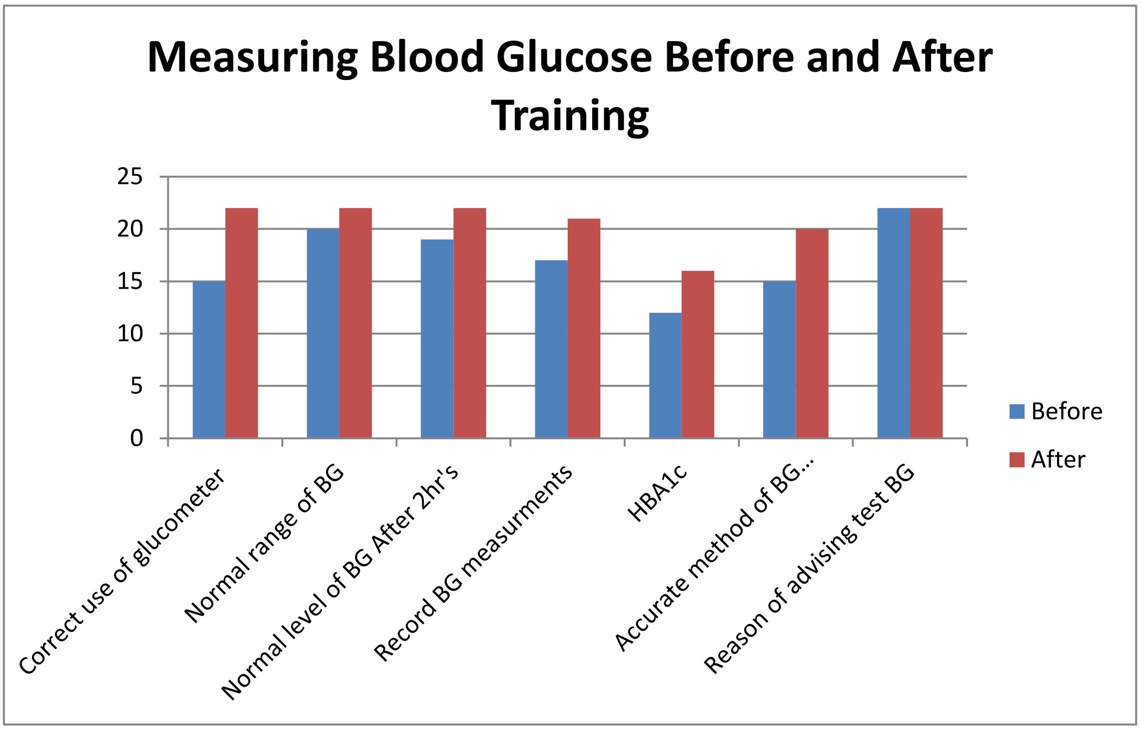

Chart 6.1: Responses before and after training for diabetes knowledge of measuring blood glucose among community pharmacists

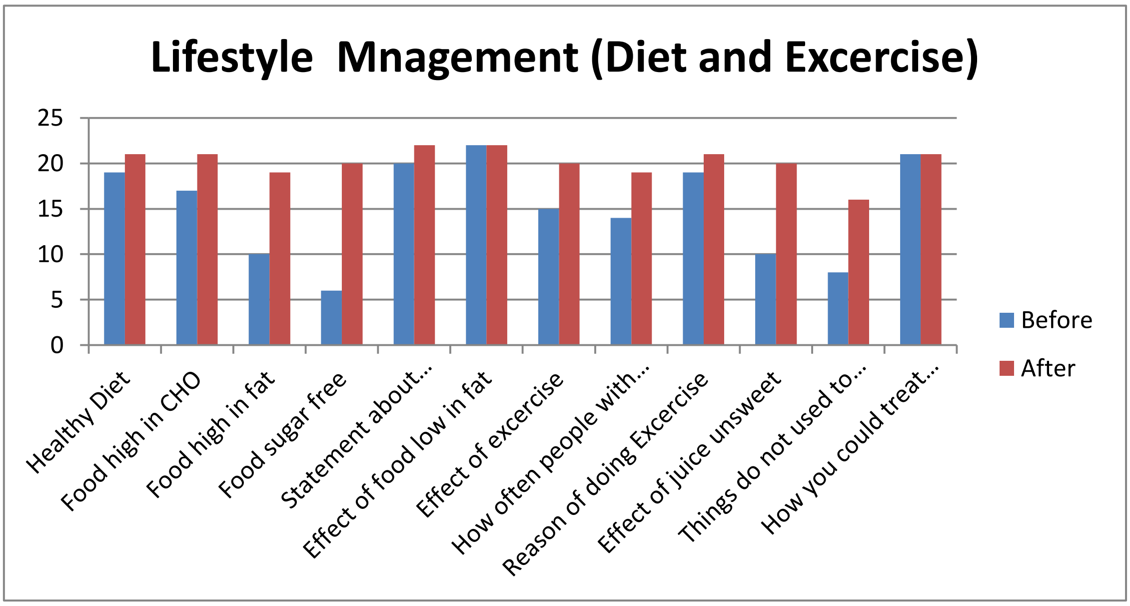

Chart 6.2: Responses before and after training for diabetes knowledge about lifestyle management

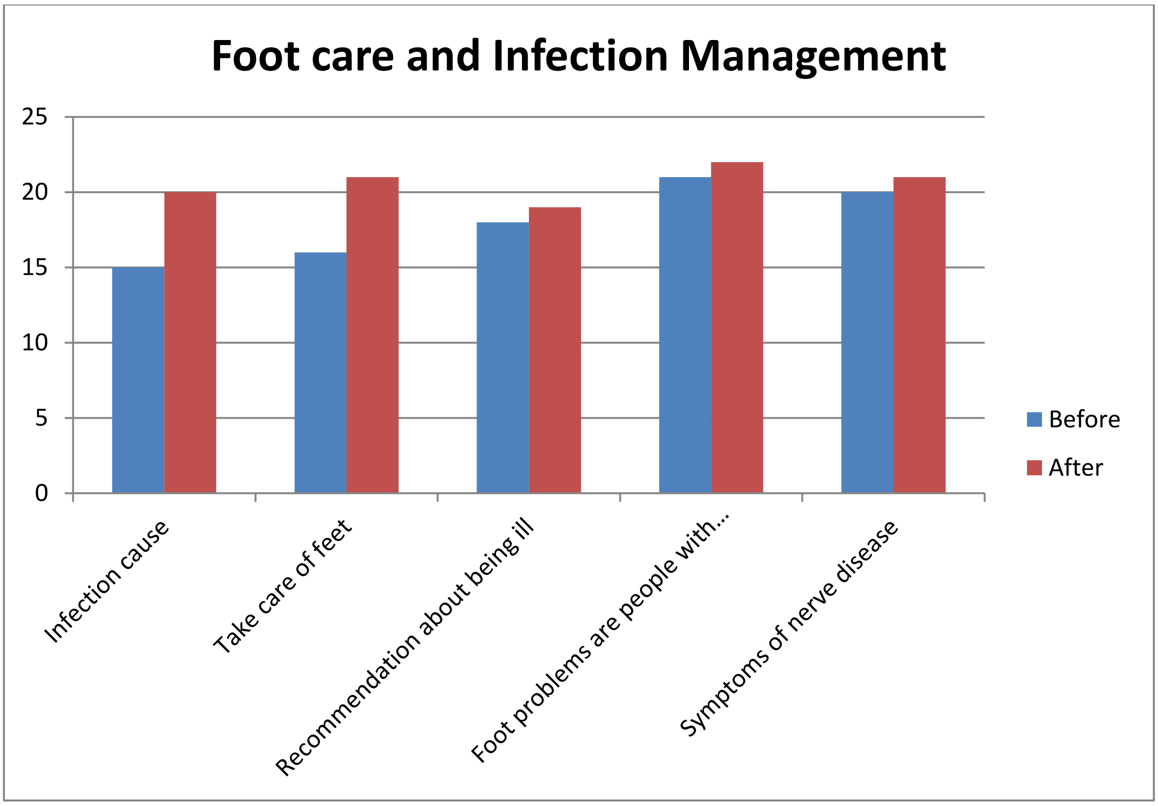

Chart 6.3: Responses before and after diabetes knowledge about foot care and infection management

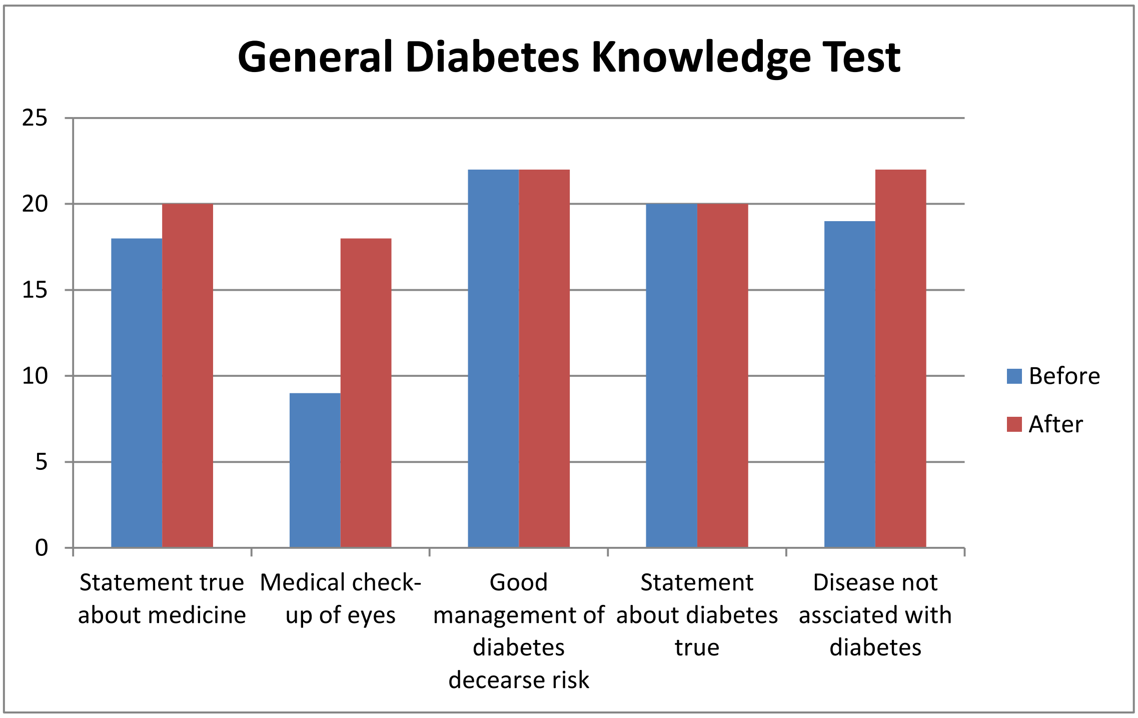

Chart 6.4: Responses before and after general diabetes knowledge test

Table 6.2: Average scores and paired samples t-test before and after intervention for the four sub-scales.

Sub-scales names	No of items	Scores Before Training			Scores after training		
		Mean±Sd	Range	P-value[a]	Mean±Sd	Range	P-value[a]
Measuring Blood Glucose	7	5.45±1.01	4-7	>0.001	6.59±0.73	5-7	>0.001
Lifestyle management	12	8.22±0.81	5-10	>0.001	11.0±0.87	9-12	>0.001
Foot care and infection management	5	4.09±0.81	2-5	0.004	4.72±0.55	3-5	0.004
General diabetes knowledge	5	4.0±1.02	2-5	0.034	4.63±0.90	2-5	0.034
Total diabetes knowledge score	29	21.63±3.0	15-26	>0.001	26.95±1.58	24-29	>0.001

[a] Paired sample t-test to show the training effect

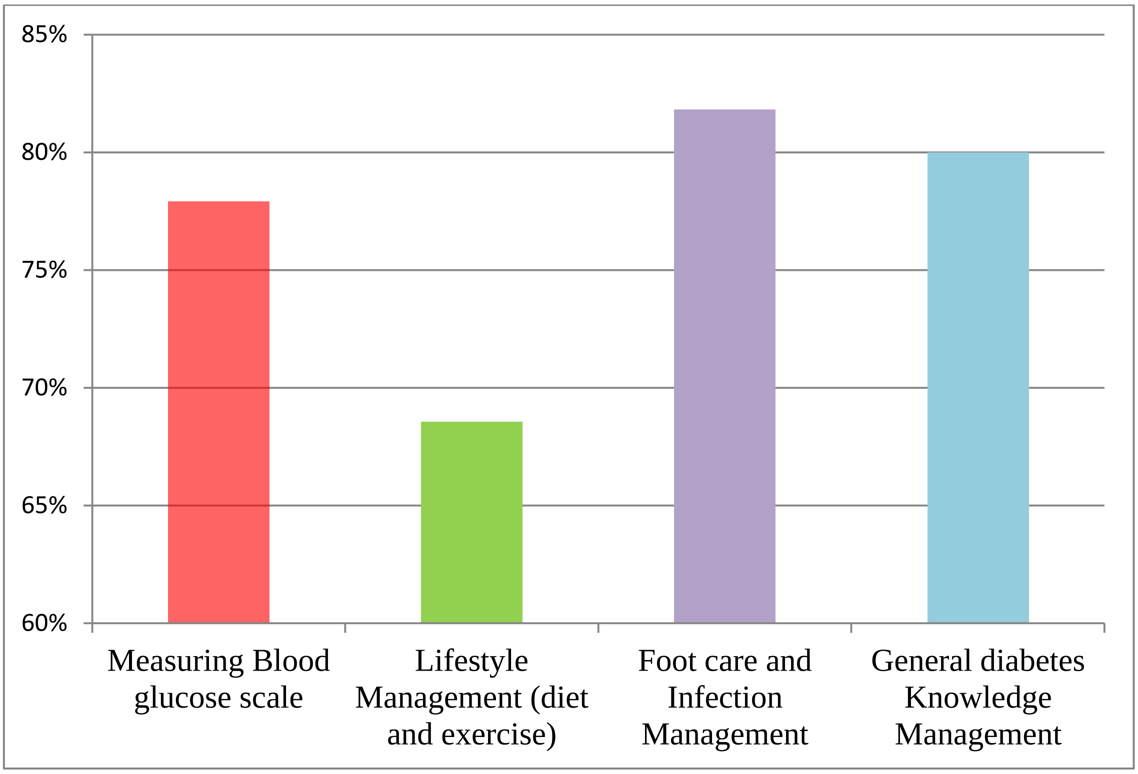

Chart 6.5: Sub-scales of diabetes knowledge test before training

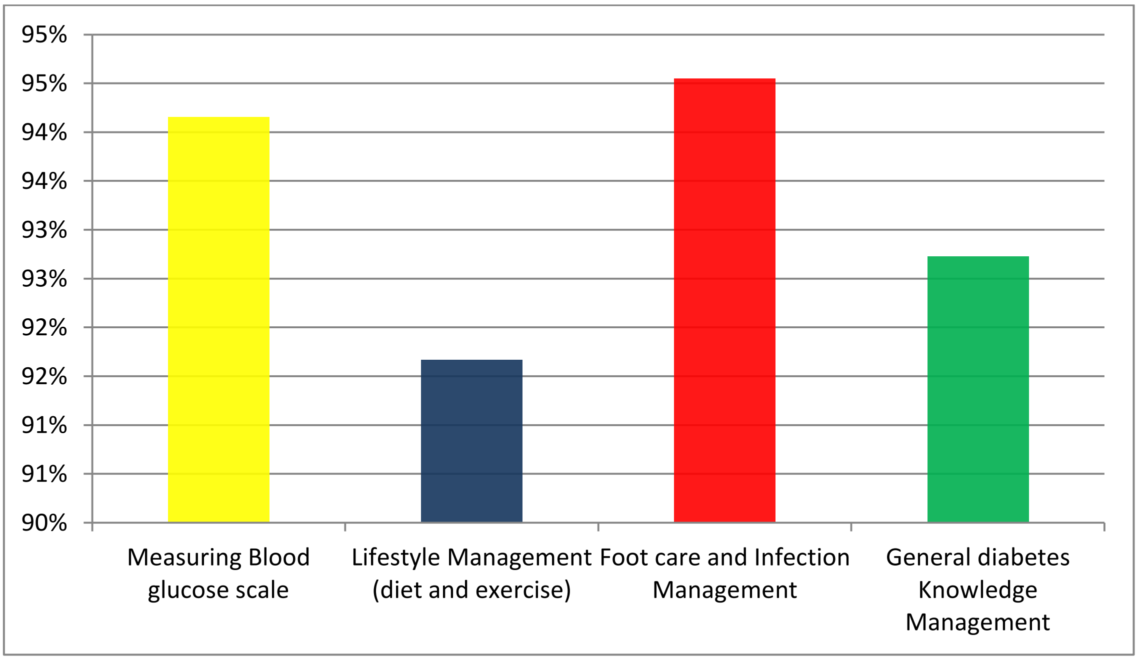

Chart 6.6: Sub-scales of diabetes knowledge test after training

6.4. Discussion

The training was successful and led to a significant improvement in overall knowledge among participants in intervention group (p-value < 0.001). Before training the pharmacists was assessed to understand their diabetes knowledge, this allowed educational material to be targeted at weaker areas of knowledge. The educational materials used in the current thesis for training purposes were easy to understand for pharmacists. There was an impact on community pharmacists' type II diabetes knowledge and their confidence.

In diabetes, health literacy is related to diabetes knowledge, self-efficacy and self-care behaviours and glycaemic control. Health literacy may also provide a better understanding of racial disparities observed in patients with diabetes. Strategies to address health literacy, based upon this understanding of its role, provide a means to improve diabetes care (Cavanaugh, 2011). The educational material provided to community pharmacists was able to (help them) improve type II diabetic patients' knowledge and attitudes. The materials cover various information regarding type II diabetes: defining diabetes, understanding complications, symptoms and how to manage hypoglycaemia, how to take medication, kinds of food to eat and to avoid.

Recognizing that low health literacy is common and associated with many facets of diabetes care including important outcomes, strategies to address health literacy have been developed, tested and promoted (Cavanaugh, 2011). The foundation of these strategies rests with the principles of clear health communication, including assessment of understanding, use of plain language, emphasizing a few key points and using effective printed materials (Kripalani and Weiss, 2006). In the current study, health literacy was taken into account by enhancing community pharmacist's knowledge and practice toward type II diabetes to increase the confidence. This then can have an impact on patients.

Although there are many resources available in brochures, fact sheet and web-based formats to deliver information to patients with diabetes, the complexity of the content, including the reading level of the text, often surpasses the skill of patients and presents a barrier for information delivery to those with low health literacy (Hill-Briggs and Smith, 2008; Kerr, 2007). The educational material that was adapted from diabetescare.net was designed for patients but it seems rather difficult for patients at different educational levels, and it was used here for community pharmacists. Recently, several diabetes materials have been developed specifically to address low health literacy and to be used interactively between patients and providers to promote patient understanding, empowerment and improved self-efficacy with self-care behaviours.

In the present study, few participants had special training about diabetes. Because pharmacists' functioning as Certified Diabetes Educators CDEs in their natural work environment is relatively new (Alzahrani et al., 2015). Even in developed countries such as Canada there are presently 3760 certified diabetes educators (CDEs) in Canada and out of these 1379 are pharmacists (Alzahrani et al., 2015). As a profession, pharmacists make up one third of all CDEs in Canada and are the quickest growing sub-division of CDEs in Canada (Alzahrani et al., 2015). Taking into account their accessibility and recent willingness to gain CDE designation, there are a vast amount of opportunities for pharmacists to get more involved in diabetes education (Alzahrani et al., 2015). In Japan, Certified Diabetes Educator of Japan (CDEJ) is a qualification obtained by nurses, dieticians, pharmacists, clinical laboratory technicians, and physiotherapists. Presently, there are approximately 11,778 certified diabetes educators in Japan (Kawaguchi, 2007).

The average score for intervention pharmacists before training was good (21.63/29) but training seems fundamental to ensure the pharmacists are able to provide pharmaceutical care for the patients. It could be argued that the items used normally assess patient knowledge, but the questions appear difficult for most patients (in this context). The Michigan diabetes knowledge test has been previously used by researchers as a measure of general diabetes knowledge. It can be a useful method for group comparisons and for assessing knowledge change over time. This test's usefulness as an outcome measure for educational interventions remains to be determined (Fitzgerald et al., 1998). The detailed data analysis showed exactly which knowledge needed to be improved in the intervention group.

6.5. Conclusion

The study shows the effectiveness of educational materials used to enhance diabetes knowledge among participants, even though the community pharmacists began with relatively good knowledge. But it was essential to do training to ensure the pharmacists in the randomised controlled trail had outstanding knowledge.

6.6. Chapter summary

The key point of current chapter is that the community pharmacist enhanced their diabetes knowledge during participation in the study. In **Chapter 7** the randomised clinical trial is described

The Effectiveness of Community Pharmacists in Tripoli /Libya in Managing Patients with Type II diabetes by Improving Their Glycemic Control, Knowledge, Attitudes and Self-Care Behaviour via Randomised Controlled Clinical Trial

This chapter provides the reader with the specific analysis and results of clinical trial intervention. In order to understand poor glycaemic control among people having type II diabetes it is essential to evaluate diabetes knowledge, attitudes and self-management. This enables the researcher to identify reasons of poor glycaemic control, and therefore, modify the required intervention to improve glycaemic control among participants.

This chapter is structured into: an introduction **(Section 7.1)** that briefly describes the effectiveness of community pharmacists in relation to type II diabetes care and approaches to clinical trial intervention; the methods and study design provided in **(Section 7.2);** the results from participants **(Section 7.3)**; discussion **(Section 7.4);** conclusion **(Section 7.5);** and chapter summary **(Section 7.6).**

The randomised controlled clinical trial is an ideal experimental method for the evaluation of the effectiveness of health services and interventions in relation to specific conditions.

Abstract

Objective: An association between improved glycaemic control and a sustained decrease in the rate of diabetic complications has been shown in randomized clinical trials. The main aims of study are to improve glycaemic control via the community pharmacist intervention. Enhance effectiveness of community pharmacist diabetes medicine management by engaging pharmacist assist diabetic patient to improve patient's diabetes knowledge, self-management and attitudes.

Methods: 40 community pharmacies were randomly assigned to be control (18) or intervention (22) premises. Then each pharmacy recruited 4 or 5 type II patients with diabetes. Overall, 225 patients were recruited and assigned to receive usual pharmacist care (n=100) or a predefined pharmacist intervention (n=125). Each patient completed a questionnaire in which demographic information, disease history, medication history, diabetes knowledge and self-care activity levels were collected. At inclusion patients measured their fasting plasma glucose (FPG) on three consecutive days. The data was analysed by IBM SPSS Statistics 22.

Results: the time effect of intervention shows that the FPG decreased significantly in the intervention group ($P \leq 0.001$) as well in the control group ($p=0.004$). However, the intervention effect on FPG was not significantly improved with P- value (0.268). HbA1c of patients in the intervention group decreased significantly during the 6-month study period ($P \leq 0.001$), and HbA1c of the control group patients was also reduced, but not significantly ($P = 0.0622$). However, the differences between control and intervention group in HbA1c were not significant ($P= 0.1424$). In patients diabetes knowledge there is a balance between intervention effect and time effect (i.e. there was significant improvement in the intervention group with p value 0.031). Diabetes self-management improved significantly in blood glucose measurements ($P \leq 0.001$) and physical exercising ($P = 0.001$). The diabetes attitude toward value of tight control improved ($P \leq 0.001$).

Conclusion: The differences between control and intervention group in HbA1c and FPG changes were not significant. However, time effect before and after study showed improvement in glycaemic control for intervention group.

7.1. The effectiveness of community pharmacists in relation to type II diabetes care and approaches to clinical trial intervention

Diabetes is further complicated by a multitude of other factors, such as, the 'chronic' nature of the disease, lifelong requirement for medications, requirement for changes in lifestyle, and the need to cope with social, cultural and psychological distress that may occur with the disease (Sapkota et al., 2014). Ongoing patient self-management education and support are critical to preventing acute complications and reducing the risk of long-term complications. Significant evidence exists that supports a range of interventions to improve diabetes outcomes (ADA, 2015). It has been evident in some systematic reviews that pharmacist interventions improve glycaemic control in patients with type II diabetes compared with usual care and suggest that younger patients or those with higher baseline HbA1c levels may be the main beneficiaries of pharmacist care. Most studies assess that pharmacists working in different settings (outpatient clinic, hospital pharmacy and community pharmacy) are able to improve glycaemic control in patients with type II diabetes (Aguiar et al., 2016; Ayadurai et al., 2016; Collins et al., 2011; Pousinho et al., 2016).

However, in the current study a review focused on the impact of community pharmacists toward type II diabetes care (see **Chapter 2**). The findings suggested that a limited number of studies took place in the community pharmacy setting (Ali et al., 2012, Jahangard-Rafsanjani et al., 2015, Mehuys et al., 2011, Venkatesan et al., 2012, Ganawar et al., 2014, Kraemer et al., 2012

,Paulo et al., 2016, Kjeldsen et al., 2015). The impact of community pharmacists on type II diabetes is still in development.

Pharmacists can help patients with type II diabetes improve adherence to antidiabetic medications. Interventions to help improve medication adherence generally included an educational strategy combined with one or more other strategies to address behavioural, affective and provider-related issues of adherence (Omran et al., 2012; Collins et al., 2011). Medicaition adherence is measured as a self-management/self-care behavioural outcome at the same time as other measures, for instance adherence to diet, exercise, foot care, and blood glucose testing. In the current thesis the assessment of adherence focused on lifestyle changes by using Summary of Diabetes Self Care Activities (SDSCA). Patient self-report, pharmacy refills and claims data and electronic measures were also used to assess adherence. A range of tools are available to measure medication adherence, each having their own pros and cons (Osterberg, and Blaschke, 2005). The choice generally depends on the ease of use, validity and reliability (Horne et al., 2005). Overall, self-report tools were the more common tools used in the studies reviewed, as seen in most adherence studies (Lehmann et al., 2014). Self-report tools are popular because of their flexibility, ease of use, cost effectiveness and ability to gather social, situational and behavioural data (Lehmann et al., 2014). SDSCA was the most commonly used self-report tool to estimate adherence in type II diabetes patients. In addition to the inherent advantages that SDSCA has as a self-report tool, include being brief, reliable and valid for use in both research and clinical practice (Toobert et al., 2000).

One of the main components to provide pharmaceutical care services is training for community pharmacists. Most studies reviewed provided the pharmacist with specific training to comply with components of the study intervention (Ali et al., 2012; Jahangard-Rafsanjani et al., 2015; Mehuys et al., 2011; Ganawar et al., 2014; Kraemer et al., 2012; Kjeldsen et al., 2015). The training was focusing on pharmacotherapy; diabetes management; and referrals for eye and foot care management. As well as training on pathophysiology, pharmacology and non-pharmacological management of type II diabetes. In the current study, training (see **Chapter 4**) was provided for pharmacists to ensure that pharmacists were able to provide pharmaceutical care service in the correct way. However, the uniqueness in this study is that pharmacists' knowledge and practice were assessed (see **Chapter 5**) before training to understand their requirements while in most reviewed studies this stage does not exist.

The impact of pharmacist interventions in diabetes care has been studied and their intervention significantly reduced patients' glycosylated haemoglobin (HbA1c) levels compared to usual care (Machado, 2007). The medicines management of type II diabetes was studied in a United Arab Emirate's military hospital for a follow up period of 12 months. The results showed better glycaemic control and a reduction of cardiovascular risk scores (Almazroui et al., 2009). Mehuys et al (2011) showed that community pharmacist intervention in the clinical management of people with type II diabetes leads to better care. The study showed that a diabetes education programme resulted in improved self-management and better knowledge of diabetes and significant reductions in Fasting Plasma Glucose (FPG).

Farmer and colleagues advocated that knowledge remains an important prerequisite to good compliance with medical therapy (Farmer et al., 2006). Attitudes and beliefs towards medications have also been found to be highly correlated to medication compliance (Wilson et al., 2006). A Saudi study reported low levels of knowledge, attitude and compliance with medications among Saudi female patients with type II diabetes, suggesting a need for sustained active patient education, support and evaluation to increase patient involvement and self-reliance in the management of diabetes (Binhemd, 1992). The authors recommended the involvement of appropriately trained and culturally aware members of the primary healthcare team in patient education and in partnership with other secondary care services (Kheir et al., 2011).

The proposition that increased knowledge about a specific health problem leads to improved adherence to treatment plans and subsequently to desirable health outcomes is not limited to Type II diabetes: educational programmes in osteoporosis were found to increase knowledge about the disease and increase self-reported adherence to pharmacological treatment over a period of time (Nielsen et al., 2010). On the basis of what has been published in the literature and what could be considered intuitively sensible, it would appear that patient's health-related knowledge, attitudes and practices constitute important constructs affecting medication adherence and medication-improving the general well-being of patients with diabetes by addressing these areas in their day-to-day interactions with the patients. In addition, pharmacists in particular because of their unique skills in therapy management, should be able to improve health outcomes by addressing the medication-taking behaviour of patients (Wu et al., 2009). Indeed, an involvement of pharmacists and other stakeholders in relevant clinical cognitive activities (including encouraging patients to self-manage their disease) had been advocated (Serrano-Gil and Jacob, 2010, Scott et al., 2007).

A clinical trial is defined by Bowling (2009) as "…an experiment with patients as participants. Strictly, however, for clinical trials to qualify for the description of a true experiment, random allocation between experimental and control groups is required."

The National Institute of Health (NIH) defines five different types of clinical trials (Kaura, 2013):

a. Treatment trials: involve testing interventions for example (drugs, a new surgery procedure, and a new radiological approach) or a combination of interventions.
b. Prevention trials: involve investigating methods for the primary prevention (methods for preventing healthy people from developing a disease), secondary prevention (methods for slowing down the progression of a disease or for treating it in its early stage whilst the patient is still asymptomatic) and tertiary prevention (methods for preventing further physical deterioration in chronic symptomatic disease states) of a disease. These methods may include drugs, vaccines, lifestyle change and so on.
c. Diagnostic trials: involve investigating better procedures or tests for diagnosis a particular disease or condition.
d. Screening trials: involve investigating ways for detecting a particular disease or health condition.

e. Quality of life trials: involve exploring ways for improving the quality of life for individuals with a chronic disease.

The current clinical trial was not a treatment clinical trial but it can be categorised as a quality of life trial. The trial focuses on improving poor glycaemic control among type II patients with diabetes via enhancing diabetes knowledge, self-management and attitudes among diabetic participants. The study approaches are:

- Enhance diabetes knowledge
- Enhance diabetes self-care behaviour among participants
- Enhance diabetic people attitudes
- Control blood glucose
- Enhance community pharmacist professionalism through employing their knowledge to help type II patients with diabetes to reach their goals

Outcomes of current study divided into two outcomes:

- Primary outcomes:
    - Fasting plasma glucose (FPG)
    - Glycated haemoglobin HbA1C
- Secondary outcomes:
    - Diabetes knowledge
    - Diabetes self-management
    - Diabetes attitudes.

7.2. Methods

The study took place in Tripoli/ Libya with a population size nearly 6 million. The study conducted in 40 community pharmacies located in Tripoli, the Arabic-speaking country and located in the western part of Libya. The pharmacists recruited according to the first stage (see **Chapter 4 & 5**) and participated voluntary for the second stage (Intervention study). Each pharmacy was asked to recruit between 4 and 5 patients. Ethics approval has been granted by the Chair of the Biomedical, Natural and Physical Sciences Research Ethics Panel at the University of Bradford (**Appendix 27**). All patients were given written study information sheet and informed consent form (see **Appendix 21& 22**).

The diabetes knowledge assessed by using Australian Diabetes Knowledge Test (Eigenmann et al., 2011); diabetes self-care activities by using Summary of Diabetes Knowledge test (Toobert et al., 2000); and diabetes attitudes by using 25 statements adopted from Michigan diabetes attitudes scale (UMDRTC, 1998) were collected from both groups at baseline. The four measurements of FPG (before breakfast, before lunch, before dinner, before sleep) were collected for three consecutive days at T0 for both groups and after three months of study at (T12 weeks) collected from the intervention group. After 6 months (T24 weeks) FPG, diabetes knowledge, self-care activities and attitudes were gathered from both groups.

7.2.1. Study design

The design of study is a randomised controlled trial. This is ideal, true experimental method for the evaluation of the effectiveness of health services and interventions in relation to specific conditions (Bowling, 2014). The reason of randomisation to assess the intervention is a simple and commonly used clinical design which compares two treatments. Usually a test therapy is compared with a standard therapy. The allocation of subjects to groups is usually achieved by randomisation.

The cluster randomisation was done to avoid sample contamination (see **Appendix 23**). According to Bowling (2014) it may be preferable, for reasons of cost or feasibility, to randomise the clusters containing individuals for instance clinics or hospitals rather than individuals themselves.

Randomisation was performed at the pharmacy level. I surveyed one hundred and eight community pharmacies in Tripoli/ Libya (see **Chapter 5**). 108 community pharmacies were recruited for the next stage of study (intervention study). Then the randomisation took place on the geographical locations of community pharmacies (see **Appendix 24**) by using Excel 2010.

There were 108 community pharmacies that agreed to take part, located in 40 different geographical areas in Tripoli/Libya. Then the Excel sheet was used to generate clusters, and the name of areas recorded in the Excel sheet. The number of areas was aggregated from 40 to 16, which were randomised into 11 control clusters and 5 intervention clusters. In the 11 control clusters there were 18 community pharmacies and in the 5 intervention clusters there were 22 community pharmacies. Thus in total, the number of pharmacies randomised was forty: eighteen control and twenty two in the intervention arm. However, because small numbers of clusters were randomized, there is a possibility of chance baseline imbalance between the randomized groups, in terms of either the clusters or the individuals (Higgins et al., 2008).

7.2.2. Patient criteria

Type II diabetes patients were recruited consecutively in the participating pharmacies. To be eligible, patients were required to have a prescription for oral hypoglycaemic medication. In consecutive order, patients visiting the pharmacy were invited to participate in the study when fulfilling the following inclusion criteria: age between 35 years and 75 years, treatment with oral hypoglycaemic medication for at least 12 months, and a regular visitor of the pharmacy. Since metformin can also be used for other indications (such as prediabetes), patients were asked for which indication they used metformin.

7.2.3. Intervention

Patients in the control group received usual pharmacist care (i.e. the pharmacist provide control group with glucometer along with FPG record sheet **(Appendix 28**). The pharmacist asked the patients with type II diabetes to record their FPG on three consecutive days at the start of study at T0 and at the end of study after six months T24weeks). Patients in the intervention group received a protocol-defined intervention at the start of study and at each prescription-refill visit (for hypoglycaemic medication) during the course of the study. The pharmacist provided patients in the intervention group with glucometer and FPG record sheet (**Appendix 28**). The pharmacist educated patients about how to use glucometer and take readings properly. The pharmacist asked patients to record their FPG in three consecutive days at T0, T12 weeks and T24 weeks. The pharmacist provided patients with Arabic educational leaflets (**Appendix 25 & 26**).

The intervention was adapted from a previous trial Mehuys et al., (2011).The components of intervention implemented were:

i. Education about type II diabetes and its complications:
ii. Education about the correct use of oral hypoglycaemic agents (timing in relation to food);
iii. Healthy lifestyle education (diet, physical exercise and smoking cessation); and
iv. Reminders about annual eye and foot examinations.

The adherence to lifestyle activities has been assessed by using Summary of Self-Care Activities (SSCA). Education about non- pharmacological aspects was provided using printed materials about diabetes (**Appendix 25 & 26**) and assessed by using Australian Diabetes Knowledge Test ADKT (**Appendix 18** (Translated Arabic version) & **Appendix 15** (English version)).

These elements were implemented by the pharmacist on each visit of the patient during the 6-month intervention period. Before the start of the study, the intervention pharmacists underwent a training session on the pathophysiology of type II diabetes and its nonpharmacological and pharmacological management according to current treatment guidelines, and the study protocol. The control pharmacists only received training on the study protocol.

7.2.4. Primary outcomes

Fasting plasma glucose: Each study participant was provided with a complimentary glucose meter (Accu-Chek), taught on its correct use, and asked to record a glucose day curve (see **Appendix 28**) (i.e., four FPG measurements ⁄ day (to ensure reliable FPG data): before breakfast, before lunch, before dinner, and before sleep), on three consecutive days. The FPG data are expressed as the mean of these 12 measurements. Patients in the control group were asked to perform these 12 FPG measurements at the start (T0) and at the end of the study (T24 weeks). Patients in the intervention arm performed the measurements every 12 weeks (at T0, T12weeks, T24 weeks), to obtain data for assessing the impact of the intervention over time. Glycosylated haemoglobin (HbA1c): At the end of the study, the community pharmacist asked each patient to provide with the current HbA1c and HbA1c for the previous 6–9 months prior.

7.2.5. Secondary outcomes

Knowledge about diabetes: Patients' knowledge about type II diabetes was evaluated at the start of the intervention period and after 6 months' follow up using an Arabic translation (**Appendix 18**) of the Australian diabetes knowledge test (Eigenmann et al., 2011).

Self-management: The diabetes self-care activities of the patients were assessed with a validated Arabic translation of the Summary of Diabetes Self-Care Activities (SDSCA) questionnaire (see **Appendix 19**), a brief self-report instrument for measuring levels of self-management across different components of the diabetes treatment ('general diet', 'specific diet', 'physical exercise', 'foot care', space carbohydrate evenly and 'smoking') (Toobert et al., 2000). The SDSCA questionnaire was completed at the start of the study and after 6 months follow-up.

Diabetes attitudes: Patient's attitudes toward type II diabetes was evaluated at the start of intervention and after six months of study follow up using an Arabic translation (**Appendix 20**) of the Michigan Diabetes Attitudes Survey (MDAS)(UMDRTC, 1998).

7.2.6. Rational for patient questionnaire

- Type II diabetes awareness questionnaire (see **Appendix 15**)
    - Section one: personal information

The general aim was to audit knowledge of diabetic people in Tripoli/Libya and also to study the burden of diabetes.

- The aim of this section was to enable me to organise data and split the data into groups
- To understand the amount of knowledge that patients with diabetes know about the disease and management. The questionnaire asked about:

1. Age
2. Gender
3. Duration of diabetes
4. Type of diabetes
5. Amount of knowledge information if the patient receives when first diagnosed; two types of information:
   a. written b. Verbal. This question adopted from (Jenny Harris et al., 2007).

- Section two: diabetes knowledge test

The aim of this section was to assess diabetic patient's knowledge in different areas of diabetic management. The items were adopted from (Eigenmann et al., 2011). The questionnaire was a validated version. The items asked about different areas of management:

1. Diet management
2. Blood glucose measurement

3. Foot care management
4. Exercise management
5. Complication of diabetes understanding
6. Hypoglycaemic management
7. Check-up management
8. Diabetic medication knowledge
9. Fact of diabetes

- Diabetes self-management (see **Appendix 16**)

To assess patients with type II diabetes self-management through the adoption of the summary of diabetes self-care activities SDSCA (Toobert et al., 2000). The SDSCA measure is a brief self-report questionnaire of diabetes self-management that includes items assessing the following aspects of the diabetes regimen: general diet, specific diet, exercise, blood-glucose testing, foot care, and smoking. The reliability and validity of SDSCA assessed by Toobert et al. (2000) in his study.

The questionnaire consists of six items related to everyday activities. The rational of using these questions are:

1. From Q1 till Q5: At first time the pharmacist met the patient after the consent form the patient and willingness to participate in the study. The pharmacists gave the patient the questionnaire then after that the questionnaire gave again to the patients. Then the data analysed for both groups.
2. While Q6: this question about Self Care Recommendations will be used to measure consistency between self-care activities and recommendations. Then series of hypothesis going to be tested as:

a. Does the patient follow the self-care activities recommendation?
b. Do patent know more about recommendation but not follow them?

- Diabetes attitudes (see **Appendix 17**)

The questionnaire used to test the attitudes toward diabetes is the third version of diabetes attitude scale has been developed by the University of Michigan Diabetes Research and Training Centre (UMDRTC, 1998). The number of items is 28 and the items divided into five discrete subscales. The subscales were attitudes toward the following:

1. Need for special training to provide diabetes care,
2. Seriousness of type 2 diabetes,
3. Value of tight glucose control,
4. Psychosocial impact of diabetes, and
5. Attitude toward patient autonomy.

7.2.7. Statistical analysis

Sample size was calculated according to the ability to detect an absolute HbA1c-reduction of 0.5% (SD=1.3) at 6 months in the intervention group compared with the control group, with 80% power at the 0.05 significance level. Based on an attrition rate of 20%, at least 121 patients were required in each study group. (Hulley et al., 2013). The online sample size calculator used to provide two-group studies assume that the groups are of equal size. (See **Table 7.1**.). Software utilities were provided by Michael Kohn.

Parameters defined as following:

- Q1: proportion of subjects in group 1

- E=effect size
- S=standard deviation in the population

Table 7.1: Sample size calculation to detect population size required to provide reliable results from clinical trial study

Alpha (Two-tailed)	Beta	Q1	Q2	E	S	E/S
0.05	0.2	0.44	0.56	0.5	1.3	0.384615384615

Z-Alpha	Z-Beta
1.96	0.84
A =	4.06
B =	7.85
C =	0.15
AB/C =	215.33
N1	95
N2	121
Total	216

The success of randomization was assessed by comparing baseline characteristics of the study groups using independent sample t-tests for continuous variables and chi-square tests for categorical variables. Outcomes for continuous variables were analysed using: paired t-tests to study the effect within each study group at T24 vs T0; and independent sample t-tests to evaluate the study group effect (i.e., mean change from baseline in the intervention group vs mean change from baseline in the control group). For categorical variables only the study group effect was investigated, using chi-square tests. The answers on domains 1–6 of the SDSCA questionnaire (ordinal data) were evaluated with the Wilcoxon signed ranks test (time effect) and a Mann– Whitney U-test (study group effect). It seemed likely that patients with poor glycaemic control at baseline would benefit the most from the intervention. Therefore, it was decided a priori to perform a subgroup analysis of the FPG change as a function of the patients' FPG at baseline. All statistical analyses were conducted with SPSS version 22. A two-tailed significance level of 0.05 was used.

7.3. Results

The results collected from 225 patients with type II diabetes are provided in this section. The results include:

- demographic profile of participants in terms of age, duration of having diabetes, level of education, number of smokers, number of hypoglycaemic tables taken to control blood glucose or insulin users and measurements of fasting plasma glucose and glycated haemoglobin.

- Diabetes awareness data compromise of fifteen questions subscales into thirteen as following; Diabetes definition, Infection management, Reasons of exercise, Understanding of neuropathy complication, Reasons of test Blood Glucose, Understanding diabetes complication, Understanding eye check-ups, Understanding of diet plan, Recording Blood Glucose (BG) measurements, Medication checks, Normal range of BG postprandial, Frequency of exercise, Hypoglycaemic management, Normal range of BG pre-prandial, Practical Method of test BG.
- Diabetes self-care activities data the activities divided into seven scales are; General diet, Foot care, Physical exercise, Specific diet, Blood glucose measurements, space carbohydrate evenly, Smoking status.
- Diabetes attitudes subdivided into six scales of attitudes are; Seriousness, Impact of patient lives, Value of tight control, Patient Autonomy, Need for special training and Psychosocial Impact.

7.3.1. Recruitment and follow up diagram

The control pharmacies recruited 100 participants whereas the intervention pharmacies recruited 125 participants. Nearly all patients completed the study (control group: 97⁄100; intervention group: 121⁄125). Reasons for non-completion were: lost to follow up (5) and hospitalization (2). The flow chart of participants through the study highlighted in (**Figure 7.1**)

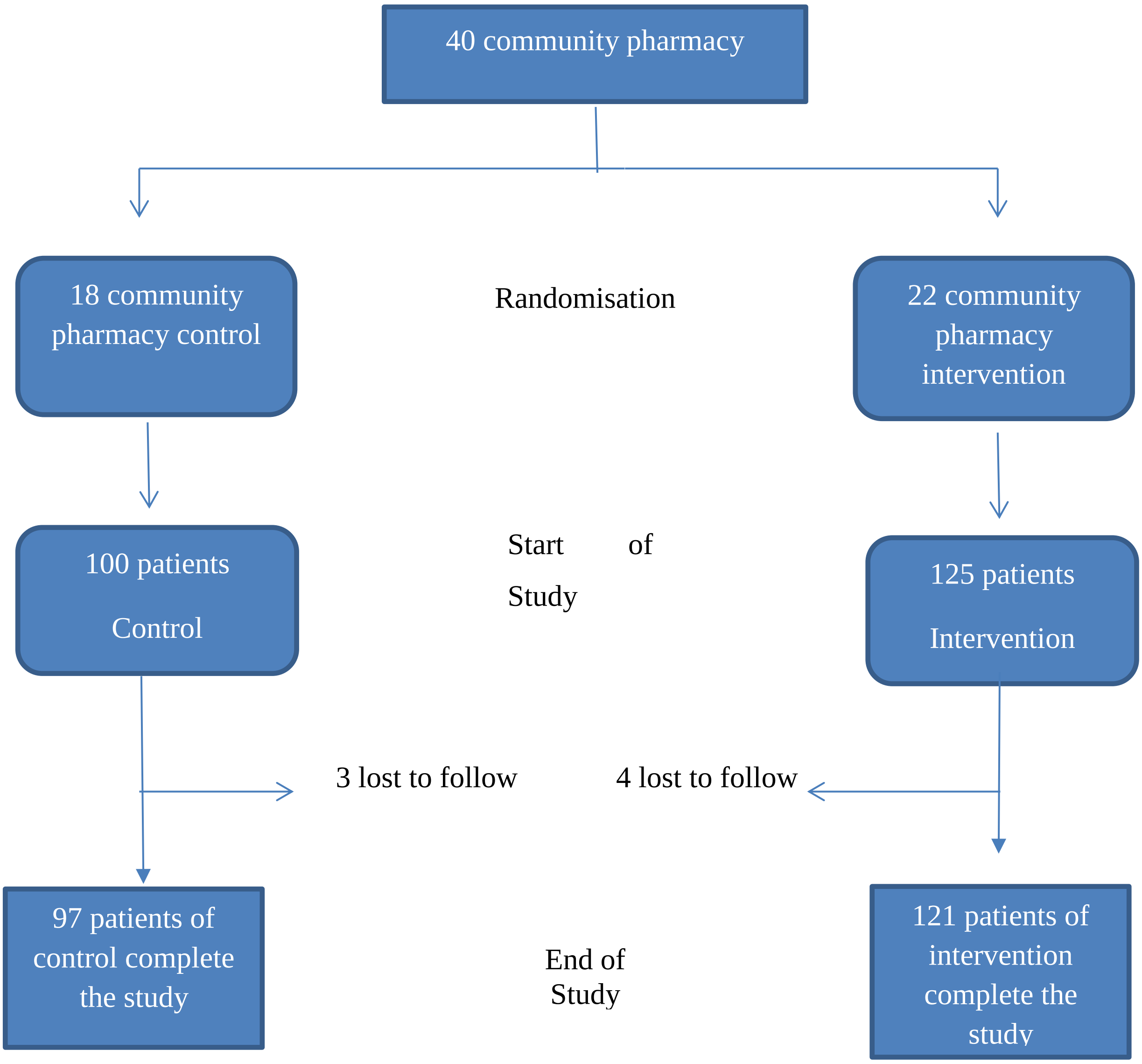

Figure 7.1: Flow chart of randomised controlled clinical trial

7.3.2. Participant's demographic data

Table 7.2 shows the demographic characteristics of participants. Overall number of participants 225 patients with type II diabetes splits into two groups control and intervention groups. Each group compromises of (100 patients) control and intervention (125 patients). Control consist of (42% men and 58% women) vs intervention (45% Men and 55% Women). There were no baseline differences in mean (± s.d.) age (56±13 vs. 55±12.3) or duration of having diabetes (7.7±6.1 vs. 7.52±4.88). There was low number of participants with no education with nearly same baseline in both groups (6 % (6) vs 6% (8)). While, the highest number of respondents acquire primary education at (41% (41) vs 40 % (50). Low smoking status among participants in both groups (12% (12) vs 18% (23)). The highest number manage their blood glucose with one tablet in both groups are (46% (46) vs 45% (55) and low number using insulin in both participants (3% (3) vs (5% (6)). There were no baseline differences in mean FPG (176.88±41.30mg/dl vs 177.93±39.69mg/dl). The baseline FPG is much higher than the normal range of 90-130 mg/dl, which indicates capacity to benefit from better care.

Table 7.2: Demographic Characteristics for patients with type II diabetes in both control and intervention groups

Parameter	Control group (n=100)	Intervention group (n=125)
Male Female	42% (42) 58% (58)	45% (56) 55% (69)
Age (years)	56±13 (35-80)[a]	55.22±12 (37-85)[a]
Duration of having diabetes	7.7±6.1 (1-21)[a]	7.52±4.88 (1-25)[a]
Education No education Primary school Secondary school High education (i.e. BSc, MSc)	 6%(6) 41% (41) 33% (33) 20% (20)	 6% (8) 40% (50) 32% (40) 22% (27)
Smokers	12% (12)	18% (23)
People manage their blood glucose control with: One tablet Two tablets Three tablets	 46% (46) 38% (38) 9% (9)	 45% (55) 36% (45) 11% (13)
Insulin users	3%(3)	5% (6)
FPG (mg/dl)	176.88 ± 41.30 (107.5-372.9)	177.93±39.69 (107.5-372.9)
HbA1c (%)	7.8 ±1.38[b]	7.9 ± 1.6[b]

[a] Range of age and duration of having diabetes
[b] HbA1c at baseline was available for 44% of the control group patients and for 50% of the intervention group patients.

7.3.3. Fasting plasma glucose and glycated haemoglobin results

There were not signification changes between control and intervention (p=0.268) with a mean decrease of 11.4 mg/dl (7.1 to 15.7 mg/dl, P<0.001) in the intervention group compared to a decrease of 7.7mg/dl (2.6 to 12.8 mg/dl, p=0.04) in the control group (**Table 7.3**). The time effect was significant (before and after) whereas the intervention effect was not significant (control and intervention). The proportion of patients having an FPG between 90 and 130 mg⁄dl (ADA glycaemic target) was increased in both study groups (control group: +5.1%; intervention group: + 15.7%).) (**Table 7.3**).

7.3.4. HbA1c

The baseline and final HbA1c values for 43 patients of the control and 60 patients of the intervention. Patients' demographic and clinical parameters at baseline did not significantly differ as a function of the availability of HbA1c values. There was also no difference in FPG at the end of the study between both groups. For the primary outcome, HbA1c there was no significant difference between the two study groups (p=0.1424) with a mean absolute decrease of 0.53% (CI: 0.28%, 0.79%, p<0.001) in the intervention group compared to a decrease of 0.26% (CI: 0.14%, 0.53, p=0.0622) in the control group (**Table 7.3**). In other words, the data suggested that the intervention effect was not significant but time effect was significant. The duration of study was only six months, and the intervention effect might have improved if the duration was more than six months.

	Control group (n = 97)			Intervention group (n =121)				
Parameter	0 months	24 weeks	Mean change[a]	0 months	12 weeks	24 weeks	Mean change[a]	Difference [b](95% CI) , p-value
FPG (mg/Dl)	176.93 ±53.1	169.2 ± 44.4	-7.7 (-2.6 to –12.8)	177.93±59.6	172.76±50.9	166.51±45.2	-11.4 (-7.1 – 15.7)	-3.7 (-10.3 to - 2.9)
			p = 0.004[a]				p <0.001[a]	p = 0.268[b]
FPG within 90-130 mg/dL range (% patients)	19.6%	24.7 %	-------	21.5%	26.4%	37.2 %	--------	-2.08 (-10.4 to 6.2) P =0.618 Chi-Square p=0.001[c]
HbA1c (%)	7.8 ±1.38	7.5 ±1.24	- 0.26 (-.014 to 0.53)	7.9 ± 1.6	…………	7.4 ± 1.3	-0.53(-0.79 to-0.28)	-0.28 (-0.65 to 0.095)
			p = 0.0622[a]				p <0.001[a]	p = 0.1424[b]
HbA1c <7 % (% patients)	11.6%	14%	-------	11.7%	…………..	30%	--------	0.58 (-0.09 to 1.24) p= 0.0767[b]
HbA1c <8 % (% patients)	51%	63%	-------	42%	…………	63%	-------	-0.24(-0.68 to 0.20) p = 0.2795[b]

Table 7.3: Fasting plasma glucose and HbA1c measurements to show glycaemic control among participants

[a] Mean change from baseline 'time effect' (95% CI), P value. (paired sample t test)
[b] Difference in mean change from baseline between intervention and control group 'intervention effect' (independent-sample t test)
[c] Chi-Square test to show the significance of FPG intervention effect in both groups

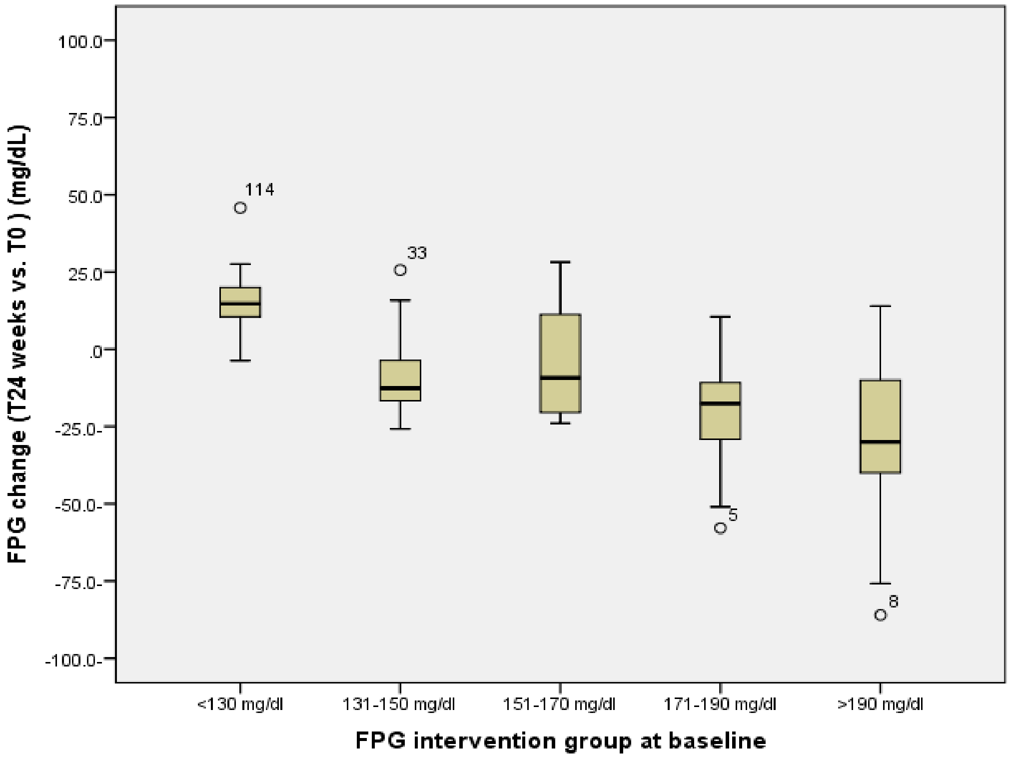

Figure 7.2: Box plot for the Fasting Plasma glucose change between baseline and at the end of study for intervention group

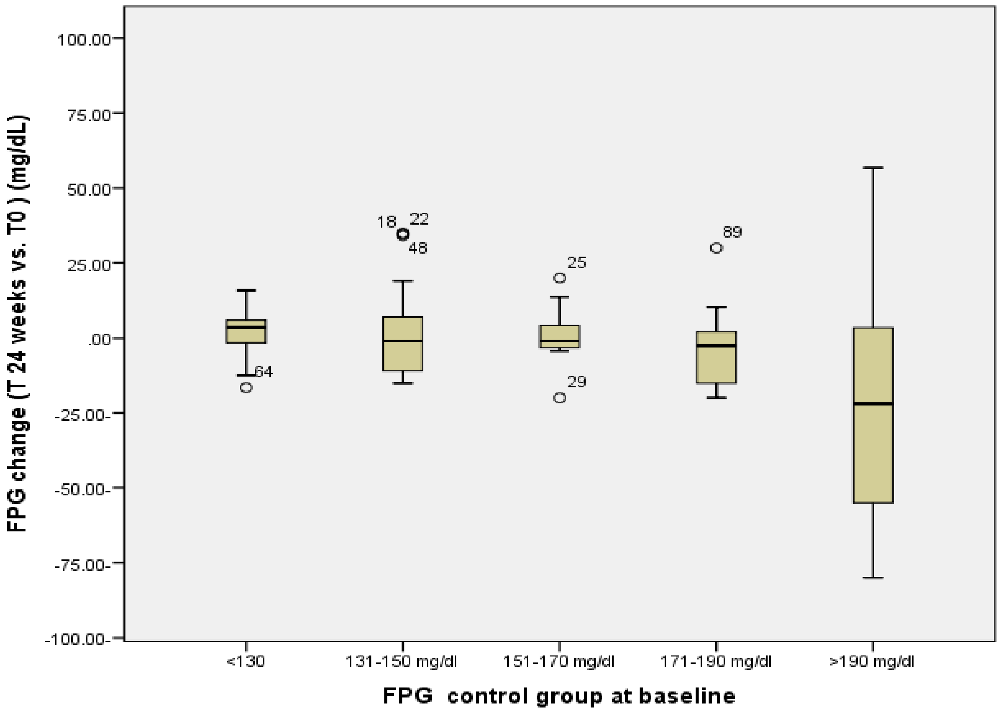

Figure 7.3: Box plot for the Fasting Plasma glucose change between baseline and at the end of study for control group

7.3.5. Diabetes knowledge Test responses

Patients' knowledge differed significantly between intervention and control groups (p=0.031).For the time effect the data shows there were significant improvement in the intervention group (knowledge score: +0.33, p=0.003) see (**Table 7.4**). In the control group, knowledge scores showed a small, but non-significant improvement (knowledge score: +0.13, p >0.1). The detailed diabetes knowledge test (see **Table 7.5**) shows that the diabetes knowledge among participants seems to be poor at T0 or at baseline. The lowest knowledge in defining diabetes at (4% vs 5%), infection management (11% vs 22%), reasons of doing exercise (16%vs 20%) and understanding of neuropathy complication (17% vs 21%). The highest knowledge exists in practical methods of testing blood glucose (88% vs 87%) and normal range of blood glucose pre-prandial (73% vs 74%). The awareness of Medication checks (50% vs 52%), Normal range of BG postprandial (51% vs 52%), Frequency of exercise (60% vs 61%), and hypoglycaemic management (65% vs 66%). After six months of intervention it shows there is some improvements in defining diabetes in both groups control and intervention (11% vs 23%), awareness of flu infection (17% vs 40%), reasons of exercising (21% vs 25%), foot care management (26% vs 27%), Reasons of testing Blood Glucose (47% vs 30%), Understanding diabetes complication (39% vs 41%), Understanding eye check-ups (37% vs 43%). The knowledge of understanding diet plan increased in control group at 64% vs 46% in intervention group. While, awareness of normal range of BG postprandial improved in intervention gr (64%) vs control group (41%)

	Control group (n = 97)			Intervention group (n =121)			
Parameter	0 months	24 weeks	Mean change[a]	0 months	24 weeks	Mean change[d]	Difference (95% CI)[b] , p-value
Knowledge test score (15)	6.21 ± 2.5	6.34±2.7	0.13(-0.38–0.11) p = 0.292	6.70 ± 2.2	7.02±1.7	0.33 (-0.55-0.11) p =0.003	0.24 (0.47-0.02) p= 0.031
Knowledge test score (%, 0-100)	41.37% ± 16.9	42.27% ± 15.2	0.89 (-2.6 -0.78) p = 0.292	44.6%±14.4	46.8%±11.5	2.20 (-3.6 -0.73) p = 0.003	1.7(3.1-0.15) p= 0.031

Table 7.4: T-test of type II diabetes knowledge among participants

[a] Mean change from baseline 'time effect' (95% CI), P-value measured by paired sample T- test
[b] Difference in mean change from baseline between intervention and control group 'intervention effect' measured by Independent t -test (intervention effect)

Table 7.5: The Detailed Diabetes Knowledge Test

Questions about:	Control T0 Correct answers	Control T24 Correct answers	Mean change Control group	Intervention T0 Correct answers	Intervention T24 Correct answers	Mean change intervention group
Mean±SD	6.2±2.5	6.31±2.25	0.13	6.69±2.16	7.02±1.72	0.33
Diabetes definition	4(4%)	11(11%)	7	6(5%)	28(23%)	22
Infection management	11(11%)	17(17%)	6	27(22 %)	48(40%)	21
Reasons of exercise	16(16%)	20(21%)	4	25(20%)	30(25%)	5
Understanding of neuropathy complication	17(17%)	25(26%)	8	26(21%)	33(27%)	7
Reasons of test Blood Glucose	24(24%)	46(47%)	22	34(27%)	36(30%)	2
Understanding diabetes complication	31(31%)	38(39%)	7	45(36%)	50(41%)	5
Understanding eye check-ups	33(33%)	36(37%)	3	43(34%)	52(43%)	9
Understanding of diet plan	46(46%)	62(64%)	16	60(48%)	56(46%)	-4
Recording BG measurements	47(47%)	41(42%)	-6	79(63%)	68(56%)	-11
Medication checks	50(50%)	43(44%)	-7	65(52%)	57(47%)	-8
Normal range of BG postprandial	51(51%)	40(41%)	-11	65(52%)	78(64%)	13
Frequency of exercise	60(60%)	52(54%)	-8	76(61%)	62(51%)	-14
Hypoglycaemic management	65(65%)	50(51%)	-15	83(66%)	71(59%)	-12
Normal range of BG pre-prandial	73(73%)	53(55%)	-20	93(74%)	85(70%)	-8
Practical Method of test BG	88(88%)	79(81%)	-9	109(87%)	96(79%)	-13

7.3.6. Diabetes self-management activities results

At the end of the study, intervention-group patients showed significant improvements in the domains of foot care (+0.19, $p>0.001$), blood glucose measurement (+0.52 day ⁄ week, $p=0.01$), physical exercise (+0.23day ⁄ week, $p=0.021$), general diet (+0.28 day ⁄ week, $p=0.032$), space carbohydrate evenly (+0.26, $p= 0.035$), and specific diet (+ 0.24, $p=0.047$) (**Table 7.5**). For patients in the usual care group, no improvement was seen in any of the six domains. There was a significance between-study group difference regarding the domains of blood glucose measurement ($p<0.001$), physical exercise ($p=0.001$) and foot care ($p=0.025$). There is no significant difference on specific diet, general diet and space carbohydrate evenly.

7.3.7. Patients attitudes toward type II diabetes

At the end of the study, intervention group patients showed slightly better attitudes at impact of patients' lives ($p=0.01$), patient autonomy ($p=0.031$) and seriousness ($p=0.033$). While, patients in the usual care no attitude improvements seen (**Table 7.7**). However, there is significant improvement in value of tight control between study groups ($p\leq0.001$). The impact of patient lives is significantly enhanced between groups ($p=0.016$), patient autonomy ($p=0.021$) and seriousness ($p=0.003$).

Table 7.6: Diabetes Self-care activities

Self-management	Control group at T0	Control group at T24	Mean change [a], p-value [b]	Intervention group at T0	Intervention group at T24	Mean change [f], P-Value [g]	Difference 95% CI, P-value [c]
General diet, scale 0-7	2.49 ±1.73	2.53 ±1.68	0.04 P = 0.839	2.59 ±1.58	2.87 ±1.42	0.28 P = 0.032	P = 0.036
Foot care, scale 0-7	3.23 ±1.97	3.36 ±1.53	0.13 P = 0.05	2.71 ±1.65	2.90 ±1.10	0.19 P = 0.009	P = 0.025
Physical exercise, scale 0-7	2.15 ±2.02	2.21 ±1.73	0.06 P = 0.566	2.49 ±1.82	2.72 ±1.28	0.23 P = 0.021	P = 0.001
Specific diet, scale 0-7	3.95 ±1.14	3.92 ±1.16	-0.3 P = 0.682	4.05 ±1.05	4.29 ±0.91	0.24 P = 0.047	P = 0.006
Blood glucose measurments, scale 0,7	2.79 ±1.81	2.82 ±1.64	0.03 P = 0.968	3.28 ±1.99	3.80 ±1.52	0.52 P = 0.01	P <0.001
Space carbohdrate evenly, scale 0,7	2.77 ±2.19	2.71 ±1.79	-.0.06 P = 0.623	2.61 ±1.99	2.87 ±1.64	0.26 P = 0.035	P = 0.426
Smoking status	11%	11%	_	18%	18%	_	_

[a] Mean change between control and intervention
[b] Wilcoxon signed ranks test measuring time effect
[c] Mann–Whitney U-test measuring intervention effect

Table 7.7 : Type II diabetes attitudes

Parameter	Control group (n = 97)			Intervention group (n =121)			
Attitudes scales	0 months	24 weeks	Mean change[a], p value[b]	0 months	24 weeks	Mean change, p value	Difference (95% CI)[c] , p-value
Seriousness	3.5 ±0.6	3.6 ±0.6	0.1 p = 0.117	3.7 ±0.6	3.8 ±0.6	0.1 p = 0.033	p = 0.003
Impact of patient lives	3.3 ±0.6	3.2 ±0.7	-0.1 p = 0.129	3.3 ±0.6	3.4 ±0.6	0.1 p = 0.01	p = 0.016
Value of tight control	3.2 ±0.6	3.1 ±0.6	-0.1 p= 0.194	3.9 ±0.5	4.0 ±0.5	0.1 p= 0.036	p<0.001
Patient Autonomy	4.1 ±0.5	4.0 ±0.5	-0.1 p = 0.506	3.8 ±0.5	3.9 ±0.5	0.1 p = 0.031	p = 0.021
Need for special training	4.3 ±0.6	4.3 ±0.6	0 p = 0.491	4.4 ±0.6	4.4 ±0.6	0 p = 0.936	p = 0.095
Psychosocial Impact	3.9 ±0.7	3.9 ±0.6	0 p = 0.625	4.0 ±0.7	4.0 ±0.7	0 p = 0.229	p = 0.288

[a] Mean change between control and intervention
[b] Wilcoxon signed ranks test measuring time effect
[c] Mann–Whitney U-test measuring intervention effect

7.4. Discussion

Our study shows that the time effect was significant in the intervention group ($p<0.001$) for HbA1c and FPG. While, for the control group change in FPG ($p=0.004$) was significant and change in HbA1c was not ($p=0.0622$). However, the intervention effect was not significant for both FPG ($p=0.268$) and HbA1c ($p=0.124$). These findings were agreed with Paulo et al (2016) who found that glycated haemoglobin ($p=0.143$) and FPG ($p=0.125$) did not change significantly, and Kraemer et al (2012) (HbA1c, p= 0.0757; FPG, p= 0.08552). The effectiveness of community pharmacists in relation to glycaemic control has been studied in various contexts (Ali et al., 2012, Jahangard-Rafsanjani et al., 2015, Venkatesan et al., 2012, Mehuys et al., 2011, Kraemer et al., 2012, Paulo et al., 2016).

It could be argued that the duration of studies has an impact on intervention effect. The studies with a duration longer than six months have better intervention effects ($p<0.001$, Ali et al., 2012) ($p=0.009$, Mehuys et al., 2011). However, the sustainability of primary outcomes studied by Mehuys et al (2011) suggested that HbA1c after eighteen months was not significantly changed even though more patients in the intervention arm reached a target HbA1c <7% than in the control group (53.3% vs. 39.1%).

For the secondary outcomes the diabetes self-care activities improved in exercising (p=.0.001) and blood glucose measuring ($p<0.001$). The attitude that improved was value of tight control ($p<0.001$). This finding could mean a better attitude towards tight control improves adherence to blood glucose measurement. Diabetes knowledge improved significantly in both groups (P=0.03).

The efforts to improve the care of patients have focused on a team approach in which professionals from multiple disciplines use their specialized training to make significant contributions to patient care (Clemmer et al., 1998, Papa et al., 1998). With the advent of pharmaceutical care, pharmacists have focused their services on the care of the patient and have become integral members of care teams.

Many studies suggest that coordinated care between physicians and pharmacists can improve patient care outcomes (Boudreau et al., 2002, Borenstein et al., 2003). That is, pharmacists often can impact patient outcomes through a cooperative relationship with a patient's physician (Zillich et al., 2004). However, the current study argues for an implementation of structured physician-pharmacist collaboration in primary care.

Treatment of hyperglycaemia is one of the main priorities in type II diabetes patients; an HbA1c target of 7.0% (53 mmol/mol) among people with type II diabetes is reasonable to reduce risk of microvascular disease and macrovascular disease. A target of 6.5% (48 mmol/mol) may be appropriate at diagnosis. Targets should be set for individuals in order to balance benefits with harms, in particular hypoglycaemia and weight gain (SIGN, 2013). According to UKPDS, each 1% reduction in HbA1c over 10 years is associated with risk reductions of 21% for any diabetes-related end point, 21% for diabetes- related mortality, 14% for myocardial infarctions and 37% for microvascular complications (Stratton et al., 2000). No HbA1c threshold value, for risk of any complication, was reported (Stratton et al., 2000).

This implies that pharmacists should focus on these high-risk patients, who may have little contact with other health care professionals and ⁄ or require more attention in their diabetes management. The programme was welcomed by the participating patients and the low drop-out rate may indicate the patients' need for a more intensive follow-up and education on their condition. The intervention consisted of several components; it is difficult to identify the elements that contributed most to the observed improvement in glycaemic control. However, this study showed that the program enhanced the patients' practical knowledge about diabetes, as well as their self-care activities and diabetic patient's attitudes. So, it seems likely that small improvements in lifestyle contributed, at least partly, to the results. Other possible explanatory factors are the more intensive patient-pharmacist contact and the regular glucose self-measurements.

7.5. Conclusion

To sum up, the study showed that the differences in primary outcomes of HbA1c and FPG were not significant (i.e. there were no improvements in glycaemic control between intervention and control). However, the time effect shows there were differences in the intervention group before and after study for both HbA1c and FPG. HbA1c showed more improvement after six months of study in the intervention group than control. Whereas, FPG improved in both groups before and after the study. For self-activities there were significant improvements in blood glucose measurement and physical exercising. The diabetes attitudes improved towards values of tight control in type II diabetes. The findings could suggest that a longer duration of study should be considered. In addition, the community pharmacist intervention is beneficial and it seems that a little help sometimes could improve patients with type II diabetes' ability to reach to glycaemic control target This study has been completed in a developing country that lacks a systematic health care network.

7.6. Chapter summary

The effectiveness of community pharmacists support for patients with type II diabetes had been previously and recently studied (Mehuys et al., 2011, Clifford et al., 2002, Ali et al., 2012, Jahangard-Rafsanjani et al., 2015, Venkatesan et al., 2012, Kraemer et al., 2012, Paulo et al., 2016). Most studies showed that the community pharmacist could play a valuable role in type II diabetes management. This chapter describes a randomised controlled clinical trial to improve care for patients with type II diabetes. The results show that the intervention effect was not significant for either FPG and HbA1c. The study provides new insight that providing pharmaceutical care in a developing country in Libya, Tripoli shows a slight improvement in outcomes over time.

The next **Chapter 8** will discuss the whole thesis.

General Discussion and Future Studies

This chapter provides readers with the thesis discussion and conclusion; it is divided into eleven sections. The community pharmacy premises and pharmaceutical services structure is discussed in **Section 8.1** and the community pharmacist knowledge and practice towards type II diabetes survey is discussed in **Section 8.2.** The enhancement of type II diabetes care management among community pharmacists in the training stage is discussed in **Section 8.3**. The effectiveness of community pharmacists in improving type II diabetes knowledge, attitudes and self-management for patients with type II diabetes (measured by glycaemic control) is discussed in **Section 8.4**. The implications of the study for health care practice are explored in **Section 8.5.** The conclusion of stage one of the study (exploring community pharmacy premises and structure) is provided in **Section 8.6. Section 8.7** sums up the results of stage two, exploring community pharmacist type II diabetic knowledge and practice. **Section 8.8** concludes the findings of stage three, enhancing community pharmacists' knowledge of type II diabetes. **Section 8.9** concludes the findings of stage four, improvement of type II diabetes glycaemic control via a randomised controlled trial. A chapter summary is provided in **Section 8.10**. The implications of the findings for future research are highlighted in Section **8.11.**

The overall discussion can be categorised into four themes:

- Engagement and participation of patients and pharmacists.
- Co-production of care (i.e. assisted self-management).
- Improvement of self-care activities by patients with type II diabetes.

Integration of the findings from the research undertaken with the published literature will be presented. This study aimed to improve type II diabetes patients' knowledge, attitudes and practice in Tripoli, Libya. The findings show that the primary outcomes (i.e. fasting plasma glucose FPG and glycated haemoglobin HbA1c) were improved among patients with type II diabetes. The hypothesis stated that improving patient knowledge and monitoring primary outcomes (FPG and HBA1c) in patients with patients would lead to improvements in blood glucose control.

8.1. The community pharmacy premises and pharmaceutical services structure

The World Health Organisation (WHO) has always maintained that pharmacists can make a better contribution to providing healthcare (WHO 1998; WHO 1996). This is especially true in developing countries as the health needs of people there are greater and the provision of health care is limited (Smith, 2016). Pharmacists aim to provide and promote the safe use of medications. They are considered to be professionals who can give advice about managing symptoms and long-term illnesses (Smith, 2016). They have the potential to contribute more to healthcare in the future (Smith, 2016).

With the specific needs of developing countries in mind, the International Pharmaceutical Federation (FIP) set up a working party, this delivered proposals for STEPwise usage of Good Pharmacy Practice (GPP) in these nations (FIP 1998). These suggestions concentrated on four aspects of services: access to pharmaceutical employees, with a definitive point that all individuals ought to have admittance to a qualified drug specialist; the training requires of pharmacy employees, ranging from the providing of essential training for community health employees to ongoing professional development for qualified pharmacists; the promotion of high standards regarding dispensing, premises, labelling, advice-giving, pharmaceutical care and the establishment of legislation for national drugs policies (Smith, 2004).

Despite the fact that in most high income countries the role played by the pharmacist within the realm of public health is commonly accepted, this is not the case in developing countries (Krass & Bell, 2011). In many countries in the world there are no health promotions strategies and community pharmacists are viewed as shopkeepers, rather than health professionals. In most cases, there is no distinction made between prescribing and dispensing-doctors. On the other hand, community pharmacists sell a wide variety of medications and usually people will go to them first before seeking alternative health advice (Krass & Bell, 2011). Most people in developing countries pay for medication themselves, rather than being funded by the government. There is not much collaboration between pharmacies, governments and other healthcare professionals. In addition to this, the structure and organisation of pharmacies is not effective and the resources pharmacies have are limited (Krass & Bell, 2011).

In developing countries, pharmacists want to improve their status and make their role wider. Pharmacists have good qualifications and there is increasing interest from people to study pharmacy at university. Furthermore, governments are increasingly realising the importance of public-private partnerships for improving patient outcomes and achieving better cost benefits (Krass & Bell, 2011).

Pharmaceutical services in developing countries are confronted with different issues to those in developed countries (Krass & Bell, 2011). In the present study, the data showed that the community pharmacies in Libya can be found in both commercial and residential areas, as described in Chapter Four (Section 4.3.1 in Table 4.2). Compared with community pharmacies in the UK, the Pharmaceutical Services Negotiating Committee (PSNC, 2016) indicates that community pharmacies can be found on the high street at the heart of most rural villages and in the centre of the most deprived communities. The community pharmacies in Libya are widely available, but are not the same as in the UK in terms of their structure or services. When the availability of community pharmacies is wide this leads to good implications for the health of communities (PSNC, 2016).

The pharmaceutical service in Libya has been poorly documented. The current study reveals that consultation areas are scarce in community pharmacies in Tripoli. Out of 389 pharmacies, 32 (8%) pharmacies had consultation areas compared with a Northumberland survey where (out of 75 pharmacies) 71 (99%) had a consultation room, and 56 (79%) could access hand washing facilities, either in the consultation area or close to it (Everden, 2015). According to Everden (2015) a consultation room is essential to provide advanced services, e.g. Medicine Use Reviews (MURs) and many locally commissioned services. However, simple interventions such as checking patient blood glucose levels, or hypertension, or giving advice could be done even without dedicated consultation areas. There is no fundamental barrier to providing pharmaceutical care, due to a lack of consultation areas. However, the availability of consultation areas can offer some advantages. These consultation areas allow the patient and the pharmacist to interact in a setting that respects the privacy of the patients. The patient consultation areas, when used to discuss medication and other health issues, enhance the professional interaction and relationship between the patient and the pharmacist. It also facilitates and encourages patients to request and benefit from the professional input and counselling they require from the pharmacist Everden (2015).

Furthermore, having a designated area inside a pharmacy that is specifically for carrying out patient consultations will allow pharmacists to play a more integral role in the multidisciplinary team and take better care of patients. Consultations should be confidential and personal and should take place with a dedicated consultation area, which has a positive effect on patients' health through the promotion of patient education, encouraging the appropriate and rational use of medication, and therefore lowering the incidence of medication-related problems (The Pharmaceutical Society of Ireland TPSI, 2010).

Community pharmacists are the health care professionals who are the most accessible by people in communities. Patients appreciate the fact they do not have to make an appointment to see a pharmacist (NHS, 2013). Pharmacists' accessibility in regards of location, as well as long opening hours is considered to be a great benefit for the public (NHS, 2013). Furthermore, to ensure there is a correct supply of suitable products, pharmacists also provide counselling of patients when they dispense medication to them and take part in health-promotion programmes (WHO, 2016). They keep strong links with other health professionals in primary health care. In current times, an increasingly broader range of new products are used in medicine, such as high-technology biological products and radio-pharmaceuticals. In addition to this, there is also a heterogeneous group of medical devices, including some products that are analogous to medicines. Some of these require specialised knowledge for use, as they carry risks (for example, dressings, wound management products, etc.). Pharmacists have increasingly undertaken the supplementary task of making sure the quality of the products they supply is high (WHO, 2016).

8.2. Exploration of community pharmacist diabetes knowledge and practice.

The conventional role of the pharmacist is to produce and supply medication (Wiedenmayer et al., 2006). In more recent times, however, the role of pharmacist has changed into taking a more patient-centred approach. This had led to some doctors becoming increasingly concerned that their role is threatened. A study carried out in the state of Wyoming, in the mountain region of the western United States, found that physicians felt most comfortable with pharmacists' duties highlighting errors in prescription, giving patient advice, suggesting other non-prescription medications and recommending prescription medications to doctors (Ranelli and Biss, 2000). An additional study conducted in the UK revealed that doctors were happy to delegate jobs to pharmacists that they found challenging or dull, for example checking drug adherence and producing repeat prescriptions (Edmunds and Calnan, 2001). Doctors were more sceptical about pharmacists carrying out clinically orientated activities.

Pharmacists' particular body of knowledge and skills relate to the use of medicines and this falls into broad areas (Mays, 1997). All pharmacists share scientific knowledge about medicines and their clinical applications and uses (Mays, 1997). There is a body of knowledge about how to make the best use of medicines, both applied to the needs and circumstances of individual patients, for example, the selection of delivery system, advice and usage and in terms of overall efficacy and effectiveness such as development of formularies, organisation of supply. This knowledge is based primarily in the biological and physical sciences but draws crucially on various social science disciplines, including psychology, sociology and economics (Mays, 1997). Furthermore, clinical pharmacists now regularly work as part of a multidisciplinary team with physicians, nurses, technicians, nutritionists, and other health care professionals. Intensive diabetes education and care supervision has been shown to progress patient outcomes, glycaemic control and improve the standard of life of patients (McMurray et al., 2002). Pharmacists have an important role to play with regard to educating consumers on the proper use of medications. In particular, advice-giving by pharmacists on safe self-medication should be readily available (Chui and Li, 2005). In the present study, data from the diabetes knowledge test found that the median score was 21/29, with a range from 12–26 among community pharmacists, which is better than 16/23 with a range from 8 to 22 found in a previous study done by Bisheya et al. (2011).Interestingly, the present study shows that community pharmacists have better diabetes knowledge compared with a previous study conducted in 2001 in Tripoli, Libya (Bisheya et al., 2011). Following this confirmation that Libyan community pharmacists have good diabetes knowledge, the study to improve glycaemic control for patients with type II diabetes (i.e. the randomised controlled trial) was then carried out. This was despite the barrier presented by poor facilities in community pharmacy premises (lack of consultation areas).

Regardless of a lack of consultation areas, both pharmacists and patients show their willingness and readiness to participate in the next stage of study.

Recently, a study by Shrestha et al. (2015) stated that diabetes knowledge among participants was poor with mean scores of knowledge being 10.67/20 in the Michigan Diabetes Knowledge Test (MDKT). The majority of the respondents (76.5 %) scored between 0 and 12, which corresponds to poor knowledge on Diabetes Management (DM) and only 1.9 % of the respondents had good knowledge compared with the current data, which shows that the community pharmacists scored between 20-29 and 73% (79) had good knowledge. Sixty-eight respondents (21.6%) in the previous study had a moderate level of knowledge i.e. they obtained scores ranging from 13 to 16 (Shrestha et al., 2015), compared with moderate knowledge scores (14.5-19) in the current study for 27% (29).

In summary, the current data shows that community pharmacists in Tripoli, Libya have good knowledge about type II diabetes management, but the number of studies assessing community pharmacist diabetes knowledge is small. Recent studies focused on the opinion of community pharmacists about continuing educations for diabetes management in Brazil (Kauffman et al., 2015) or assessing diabetes management activities provided by community pharmacists in Alberta, Canada (Lo et al., 2016). It is fundamental to assess community pharmacists' knowledge and practice towards type II diabetes management within any (proposed) study population in order to ensure that diabetes services provided for patients with diabetes is appropriate.

8.3. The enhancement of diabetes knowledge among community pharmacists in the training stage.

This step was to ensure that community pharmacists have the knowledge to provide patients with the required advice to reduce hyperglycaemia. The training was successful and significant improvements were shown among participants in the intervention group ($p<0.001$). The diabetes knowledge test used in this study was a combination of the previously validated Australian Diabetes Knowledge Test and Michigan Diabetes Knowledge Test MDKT (Eigenmann et al., 2011, Fitzgerald et al., 1998). Before training, the pharmacists were assessed to determine their diabetes knowledge to enable shaping of the educational materials to enhance their weaknesses in knowledge. Even though the average score for intervention pharmacists revealed they had good knowledge (score 21.63/29) but training seemed fundamental. This was to improve the consistency of pharmacist knowledge in order to reduce variation in outcomes for patients.

It has been evident that in this type of intervention (controlled trial studies by community pharmacists) it is essential to provide training (Ali eta al., 2012; Jahangard-Rafasanjani et al., 2015; Mehuys et al., 2011; Ganawar et al., 2014; Kraemer et al., 2012; Kjeldsen et al., 2015). Most studies focused on training about pharmacological and non-pharmacological management of diabetes (Ali eta al., 2012; Jahangard-Rafasanjani et al., 2015; Mehuys et al., 2011; Kraemer et al., 2012).

In an ideal world, those who suffer with diabetes should be educated about the importance of self-management of diabetes (Alzahrani et al., 2015). Diabetes education is now recognised as a keystone of diabetes care and education enhances self-care and glycaemic control in those with diabetes (Mulcahy et al., 2003, Funnell et al., 2009). Health care professionals are increasingly looking for or acquiring certification to be diabetes educators to recognise them as specialised in diabetes management (Alzahrani et al., 2015). The present study data reveals that out of forty community pharmacists who took part in a survey, only 8 (20%) had received special training in diabetes. No previous study had been done in Libya to show how many health care professionals had training or whether they were certified as diabetes educators (CDE). In comparison, in Canada CDE is provided by the Canadian Diabetes Educator Certification Board (CDECB) to health care professionals (Alzahrani et al., 2015). There are presently 3760 certified diabetes educators (CDEs) in Canada and out of these 1379 are pharmacists (Alzahrani et al., 2015). As a profession, pharmacists make up one third of all CDEs in Canada and are the quickest growing sub-division of CDEs in Canada (Alzahrani et al., 2015). Taking into account their accessibility and recent willingness to gain CDE designation, there are a vast amount of opportunities for pharmacists to get more involved in diabetes education (Alzahrani et al., 2015). In Japan, Certified Diabetes Educator of Japan (CDEJ) is a qualification obtained by nurses, dieticians, pharmacists, clinical laboratory technicians, and physiotherapists. Certified Diabetes Educator of Japan CDEJ is a qualification awarded by the Japanese Certification Board for Diabetes Educator to registered nurses, registered dieticians, pharmacists, clinical laboratory technicians, physiotherapists, certified practical nurses, or dietitian. There are approximately 11,778 certified diabetes educators in Japan (Kawaguchi, 2007).

Despite the fact pharmacists have become progressively engaged with diabetes management in the recent past, pharmacists' operating as CDEs in their natural work environment is a fairly new concept (Alzahrani et al., 2015). Naturally, these pharmacists consider their main duty is to advise patients about suitable medication use. Many of these pharmacists feel very comfortable with insulin management, interpretation of self-monitoring of blood glucose (SMBG) results and insulin dose titration. This is in line with previous literature, which discovered that non-CDE pharmacists do not feel comfortable advising on insulin use (Younis et al., 2001).

The concept of pharmaceutical care is combined with treatment monitoring and the provision of medication education, and pharmacists play a more key role in delivering elements of the public health agenda, for example smoking cessation and vaccinations (Bryant et al., 2009; Paudyal et al., 2010). Community pharmacists also play a significant role in enhancing the use of medications and the management of chronic conditions. This will help to improve the quality of healthcare and to diminish the general costs of healthcare with regard to workload and time working for other healthcare professionals (Dunlop and Shaw 2002; Smith et al., 2011; Giberson et al., 2015). Furthermore, these progressive roles and duties could improve the professional status of pharmacists in terms of how other healthcare professionals perceive them and can improve the job satisfaction of pharmacists (Inch et al., 2005; Bryant et al., 2009; Paudyal et al., 2011).

Health education comprises enhancing knowledge and gaining life skills that are helpful for individual and community health. Health education is not only associated with communicating information, but also with promoting motivation, skills and confidence (self-efficacy) needed to take action to enhance health. It comprises the communication of information regarding the underlying social, economic and environmental factors that affect health, in addition to individual risk factors, risk behaviours and the utilisation of the healthcare system (Anderson & Blenkinsopp, 2016).

8.4. The effectiveness of community pharmacist in improving type II diabetes knowledge, attitudes and self-management for II patients with type II diabetes measured by glycaemic control.

Our data suggests that this study supports, but does not provide clear evidence for, the premise that pharmacist counselling for health care plan beneficiaries with diabetes results in better disease control and improved empowerment to better self-manage this disease. The time effect showed significant improvement in HbA1c and FPG compared with the intervention effect. Care was improved for patients with diabetes over the duration of the study. Our data agreed with two previous studies (Kraemer et al., 2012; Paulo et al., 2016). Patients with type II diabetes make multiple daily choices about the management of their condition, such as appropriate dietary intake, physical activity, and adherence to drugs, often with minimal input from a healthcare professional (Jarvis et al., 2010). Programmes that are aimed at educating people about self-management are increasingly focused on by healthcare professionals and are recommended for patients with type II diabetes as a way to obtain the skills needed for active responsibility in their daily management of diabetes (Rutten, 2005). Furthermore, it has been proposed that education for self-management may play a vital role in confronting opinions about health and therefore enhance metabolic control, concordance with decisions about medications, risk factors, and quality of life (Norris et al., 2002, Lorig, 2002). Pharmacists have the educational background and specific patient-related information to be actively involved in providing pharmacotherapeutic support to patients and prescribers. This support should help make pharmacotherapy as efficient and safe as possible. In many cases, the possibilities of the pharmacist are not used optimally. For example, observing patient adherence to the recommended healthcare plan is, in most pharmacies, merely a part of the routine checks that are combined with dispensing (Van Wijk et al., 2005). Rather, observing and enhancing patient adherence should be part of the primary role of community pharmacies, because out of all healthcare providers, pharmacists hold the greatest position to notice issues concerning the prolonged use of medication (FIP, 2002). Thus, most pharmacy practice research has been carried out to reveal strategies for pharmacist intervention in patients' medication-taking. Some of the strategies seem to have been successful, but others were not (Van Wijk et al., 2005).

Treatment of hyperglycaemia is one of the main priorities in type II diabetes patients; an HbA1c target of 7.0% (53 mmol/mol) among people with type II diabetes is reasonable to reduce risk of microvascular and macrovascular complication. A target of 6.5% (48 mmol/mol) may be appropriate at diagnosis. Targets should be set for individuals in order to balance benefits with harms, in particular hypoglycaemia and weight gain (SIGN, 2013). According to UKPDS, each 1% reduction in HbA1c over 10 years is associated with risk reductions of 21% for any diabetes-related end point, 21% for diabetes- related mortality, 14% for myocardial infarctions and 37%for microvascular complications (Stratton et al., 2000).

In the present study, the mean change reduction of FPG in the intervention group was significant at -11.4 (range -7.1 to -15.7) with p-value <0.001; compared with -7.7 (range -2.6 to -12.8) in the control group with p-value =0.004 (also significant). This shows that FPG improved in both groups over time. An FPG improvement in the control group was unexpected, but beneficial for patient participants. This improvement might be because the participants in the control group self-managed their glycaemic control well. Comparing our data with the Belgium study's time effect shows that FPG in both groups had significant improvement with absolute mean decrease 14.1 mg/dl (-7.0 to -21.1 mg/dl, p<0.001) in intervention compared with reduction of 8.1 mg/dl (-2.7 to -13.6 mg/dl, p=0.004) (Mehuya et al., 2011). Our study suggested that the improvement in both groups in FPG was because of increased adherence in measuring blood glucose by using a glucometer and that is evident because the mean difference was significant in self-care activities assessment (p<0.001).

This reveals that encouraging people to use a self-monitoring glucometer helps them to set their glycaemic goals and encourages them to improve their self-care activities or self-manage their diabetes. In comparison, a similar study Belgium revealed that the FPG reduced significantly in the intervention group with a mean change of -14.1 (range -7.0 to -21.10) (p-value<0.001) and a mean change of -8.1 (range -2.7 to -13.6) in the control group (p-value=0.004) (Mehuys et al., 2011). Our finding regarding improvements in FPG is consistent with Mehuys et al's (2011) study. It has been evident in a number of studies that pharmacist intervention for type II diabetes management is effective (Aguiar et al., 2016, Collins et al., 2011, Hassali et al., 2015, Omran et al., 2012, Pousinho et al., 2016, Sapkota et al., 2015).

However, the baseline FPG in the previous Belgium study (154.1mg/dl ± 44. 6 intervention; 153.9 mg/dl ± 44.7 control) group was lower than the current Libyan study (177.93 mg/dl±59.6 intervention; 176.93 mg/dl ± 53.1 control) (Mehuys et al., 2011). The variation is possibly due to cultural and genetic differences. A study conducted by Ballotari et al. (2015) aimed to compare immigrants and Italians in regards to the differences in diabetes prevalence and to assess the inequalities in disease management and glycaemic control through the use of information taken from the Reggio Emilia (a province in northern Italy) diabetes register. The findings revealed that there was a considerably higher prevalence of diabetes for High Migration Pressure Countries (HMPC) citizens than in Italians and a lower prevalence for people from High Developed Countries (HDC) countries (Ballotari et al., 2015). Diabetes prevalence was especially high for North Africans and Southern Asians. These results are in line with similar studies carried out in Europe (Carlsson et al., 2013, Hawthorne et al., 1993, Uitewaal et al., 2004, Legro et al., 1999), in Canada (Creatore et al., 2010, Khan et al., 2011), in the USA (Venkataraman et al., 2004), and in Australia (Shamshirgaran et al., 2013). The high prevalence of diabetes amongst certain ethnic groups is likely to be due to a complicated interaction of genetic and environmental factors, such as acculturation, stress, social isolation, and employment and economic problems (Creatore et al., 2010, Misra and Ganda, 2007). Furthermore, people from Southern Asia appear to be genetically susceptible to type II diabetes (Abate and Chandalia, 2001, Mohan, 2004). In addition, some researchers have proposed that vitamin D deficiency, especially pertinent to migrant groups with darker skin pigmentation, intensifies the risk of developing diabetes amongst African people (Alvarez et al., 2010, Renzaho et al., 2011).

Global studies have generated strong evidence to show that ethnicity is a significant determinant of diversity in the incidence of diabetes (Carlsson et al., 2013, Weijers et al., 1998). Furthermore, studies have revealed that many immigrants with diabetes are not being treated (Buja et al., 2013, Thabit et al., 2009), and some ethnic groups are not likely to be testing their glycaemic index and are not achieving recommended levels of glycated haemoglobin (HbA1c) (de Rekeneire et al., 2003, Sundquist et al., 2011). Similar to other diseases, the link between diabetes and migration is complex as the former is affected by ethnic, socioeconomic, lifestyle, individual factors, and the latter is affected by country of origin, reasons for migration, age at arrival, and how long they stay in the host country (Ballotari et al., 2015).

The present study showed HbA1c decreases (from T0 to T24) in the intervention group (mean -0.53%; range -0.79 to -0.28) and less decrease in the control group (mean - 0.26%; range -0.014 to -0.53). This HbA1c decrease was statistically significant in the intervention group, but not in the control group. In a Belgium study, when comparing baseline and 6 month data, HbA1c levels decreased by -0.6% (-0.3to -0.9) (p-value< 0.001) in the intervention group, and by -0.2% (-0.1 to -0.4) (p-value =0.162) in the control group (Mehuys et al., 2011).

Our data shows that poor glycaemic control and good glycaemic control could benefit from the intervention. The findings are in line with the findings of other studies (Machado et al., 2007; Mehuys et al., 2011). Our study followed the design of a Belgium study in terms of analysing data for FPG and HbA1c but there is difference in the population. For example, in Belgium the mean baseline of FPG was 153.9mg/dl in control and 154.1 mg/dl in intervention (Mehuys et al., 2012). Whereas, our FPG baseline was higher than the Belgium study for control (176.93 mg/dl) and in the intervention arm (177.93 mg/dl). As well as the percentage of people with good glycaemic control being higher in the Belgium study than the current study; it was reported by Mehuys et al (2011) that the percentage of participants having FPG within 90-130 mg/dl was 34.1% in control group and 28.1% in intervention. Whereas our data shows that the percentage of participants within normal range of FPG was 19.6%in control and 21.5% in intervention. Our programme was welcomed by the participating patients and the low drop-out rate may indicate the patients need for a more intensive follow up and education on their condition. As our intervention consisted of several components, it is difficult to identify the elements that contributed most to the observed improvement in glycaemic control. However, this study showed that our programme enhanced the patients' self-care activities, especially improvement in measuring blood glucose by using glucometer.

Studies that have involved patients with higher baseline HbA1c levels revealed better improvements throughout the course of a pharmacist intervention (Choe et al., 2005, Cioffi et al., 2004, Coast-Senior et al., 1998, Jaber et al., 1996, Nowak et al., 2002, Odegard et al., 2005, Rothman et al., 2003). The effectiveness of community pharmacists in managing type II diabetes has been studied previously (Al Mazroui et al., 2009, Clifford et al., 2002, Mehuys et al., 2011, Rothman et al., 2005, Ali et al., 2012, Jahangard-Rafsanjani et al., 2015, Venkatesan et al., 2012, Mehuys et al., 2011, Kraemer et al., 2012, Paulo et al., 2016).

Sound knowledge about medication, diet, and exercise, self-monitoring of blood glucose and treatment modifications is required for the efficient self-management of diabetes (Speight and Bradley, 2001). Nevertheless, knowledge alone does not ensure the necessary patient behaviour changes or successful self-management. It is important to evaluate diabetes-related knowledge as a significant outcome measure in diabetes education programmes (Nicolucci et al., 2000; Funnell et al., 2009). The current intervention comprised various elements; it was challenging to classify the factors that contributed most to the observed enhancement in glycaemic control. Nevertheless, this study revealed that the programme improved patients' practical knowledge regarding diabetes, and in addition it also improved their self-management activities and attitudes. Therefore, it seems probable that minor improvements in lifestyle contributed to the positive results. Other potential factors are more patient-pharmacist contact and frequent glucose self-measurements.

Previously, action taken to improve the healthcare of patients with diabetes emphasised a team approach, whereby professionals from various disciplines would utilise their professional training and knowledge to make substantial contributions to patient care (Clemmer et al., 1998, Papa et al., 1998). There is thus great potential for multidisciplinary care to enhance health outcomes and reduce healthcare costs (Wagner, 2000). Pharmacists now focus on caring for patients and have become very significant members of healthcare teams. Various studies have proposed that coordinated care between doctors and pharmacists can enhance patient care outcomes (Boudreau et al., 2002, Borenstein et al., 2003). Pharmacists can influence patient care outcomes via building a supportive partnership with a patient's doctor (Zillich et al., 2004).

Many of the successful interventions for chronic disease management comprise the doctor delegating tasks to the healthcare team members to make sure that patients receive proven clinical and self-management support services (Calkins et al., 2004, Wagner, 1997, Wagner, 1998, Altschuler et al., 2012). It has been found a healthcare team can work more effectively when another healthcare discipline joins the team, for example, a pharmacist (Bero et al., 2000) or nursing case management (Wagner, 1998). Successful chronic illness programmes usually take advantage of the diverse skills of the team (Wagner, 2000). Nevertheless, the current study generates evidence to show that type II diabetes can be managed by community pharmacists without the need for intervention from primary care professionals and this is supported by Mehuys et al. (2011).

To take advantage of the benefits of modern medical treatments, there is a need for more efficient effective interventions to help people to follow medical regimens (Hayes et al., 2002). Some interest has been shown in expanding the role of the community pharmacist so they have additional responsibilities compared to traditional roles, such as the dispensing and distributing medication, to make the role more diverse within the realm of public health (O'Loughlin et al., 1999). The pharmacy profession is progressively being documented as playing a strategic role in health promotion, based on pharmacists' in-depth knowledge of the practical use of medicines (Olsson et al., 2002). The role of the pharmacist in a multidisciplinary team should not however be overstated (Narhi et al., 2000). There are various limitations to the potential role pharmacists play in the wider health care team; for example, in some countries, pharmacists do not have the power to prescribe medications and some do not have clinical experience (O'Donovan et al., 2011). These limitations can be made worse by economic challenges, especially in developing countries (O'Donovan et al., 2011).

The complications of type II diabetes can have a negative impact on a patient's quality of life (Koopmanschap, 2002); therefore any improvements in the quality of life of a patient may suggest a lower level of complications. The reported decrease in non-adherence to medication should eventually result in a lower number of complications, which is associated with better glycaemic control (Armour et al., 2004). Long term follow up was not possible in the context of the current study, but could have provided interesting further data.

The consequences of pharmacist interventions in the existing study were positive when compared to other kinds of interventions aimed at controlling type II diabetes (O'Donovan et al., 2011). A systematic review of patient self-monitoring of blood glucose in type II diabetes reported that it was "*of limited clinical effectiveness in improving glycaemic control in people with T2DM on oral agents, or diet alone, and is therefore unlikely to be cost-effective*." (Clar et al., 2010, p: xi). Another study assessed the effect of educating patients with type II diabetes, provided by diabetes educators and dieticians, and it was reported that "overall there did not appear to be a significant difference between individual education and usual care" (Duke et al., 2009, p:3).

8.5. Implication of the study for healthcare practice

This study suggested that community pharmacists have ability to interact and counsel patients with type II diabetes. Even though, the current study reveals there were no significant improvement in HbA1c and FPG among participants caused by the intervention. The time effect suggested that gradual improvement in both primary outcomes was possible. The community pharmacists' actions show a trend towards improvement of glycaemic control by improving simple things such as self-management and providing diabetes education. Interventions on pharmacotherapy seek to overcome drug-related problems; if needed pharmacists can give feedback to doctors and provide patient education and counselling on medication. Non-pharmacotherapy interventions comprise education and counselling for diet, exercise, disease, medication adherence, and life-style changes. Even in the present study the non-pharmacological intervention carried out and the findings of study showed a trend towards being successful.

This study has two main strengths. First, it is one of the (relatively few) randomised controlled trials (RCTs) on diabetes care in the community pharmacy setting (Krass et al., 2007a, Sriram et al., 2011, Mehuys et al., 2011, Rothman et al., 2005, Ali et al., 2012, Jahangard-Rafsanjani et al., 2015, Venkatesan et al., 2012, Kraemer et al., 2012, Paulo et al., 2016). Such studies are essential to objectively assess the effectiveness of pharmacist diabetes programmes. Moreover, this is the first such trial conducted in Libya. The mixed results suggest that further research is required to identify how clinical improvements could be sustained.

There are however limitations of this study. Firstly, the researcher may have underestimated how much of an impact the intervention had. Furthermore, only patients who had been on hypoglycaemic medication for at least a year were included; those who were newly diagnosed were excluded. Nevertheless, despite the fact all the patients had already been on pharmacotherapy for one year or more, the programme still had a positive effect on patients, as they have a higher requirement for information and education. Secondly, in an RCT it is possible the effect can be underestimated as the control group may improve their performance merely by partaking in the study. Furthermore, in the current study, the patients in the control group undertook self-measurements, which may have also had a positive impact on patient outcomes (Welschen et al., 2005). Thirdly, it may have been that the patients might not have comprehensively represented the overall population of patients with type II diabetes, as their participation was voluntary. Furthermore, the researcher only recruited pharmacy customers so as to ensure follow up was possible. This convenience sampling may have meant the patients who took part were more willing to undertake self-management of diabetes, thus leading to potential bias in the results. Lastly, it was not possible to obtain HbA1c data for all participants. It has been suggested that blinding personal and participants were not convenient due to the nature of the interventions (Antonie et al., 2014; Pousinho et al., 2016; Aguiar et al., 2016). There is substantial evidence to suggest that non blinded outcome assessment can lead to biased estimates of treatment effect. It is therefore recommended that blinded outcome assessment is used to avoid this source of bias (Kahan et al., 2015). The blinding of outcomes assessment was not provided in the current study. Kahan et al (2015) found that lack of blinded assessment was not associated with the outcome type (apart from action-based outcomes), but did differ according to the assessor. It has been highlighted that blinding of outcome assessors is infrequently used and poorly reported in open clinical trials.

8.6. Conclusion for stage one

Pharmacy is evolving from a drug-centred, supply-based activity to one which is increasingly focused on the health and medication needs of patients, effective pharmacy practitioners. The main finding in this stage was that the majority of community pharmacies were private therefore the patients have to pay for their medicine. Most pharmacies were open from 9:00 am until 11:00 pm. The majority of pharmacies did not have a consultation area. Many pharmacies did not dispose of waste medicines or glucometer strips. This information helped to shape the clinical trial in terms of accessibility of community pharmacies, however, the fact that there were few consultation areas was not a barrier to further research.

8.7. Conclusion for stage two

The results suggested that community pharmacists had good knowledge about diabetes, which could be a foundation for more clinical practice. Basic provision of information for patients appeared to be good; however, there were opportunities to enhance the level of care provided.

8.8. Conclusion for stage three

To sum up, this stage showed the effectiveness of educational materials that are used to enhance diabetes knowledge among participants, even though the community pharmacist has good knowledge. However, it was essential for the pharmacists to take part in training to improve the consistency of pharmaceutical care for people with type II diabetes provided by those who entered the clinical trial.

8.9. Conclusion for stage four

This stage showed that the community pharmacist intervention was beneficial but the findings were not significant in reducing glycated haemoglobin and FPG. It seems that a little help could sometimes improve the ability of patients with type II diabetes to reach their glycaemic control target. This trial was completed in a developing country, which lacks a systematic health care network (i.e. is not an advanced developed country) and was in a state of political unrest. The main study findings are consistent with recent studies (Jahangard-Rfasnjani et al., 2015; kraemer et al., 2012; Paulo et al., 2016).

8.10. Summary

The key findings of the current study suggested that community pharmacist provision of type II diabetes care can lead to improved glycaemic control. The programme was greeted by the participating patients and the low drop-out rate may indicate the patients' need for more intensive follow-up and education on their condition. The positive outcomes are attributable to three factors: (i) the provision of clear information by the pharmacist; (ii) the patients' and pharmacists willingness to share and discuss decisions; and (iii) pharmacists' interventions included diabetes education and counselling on drug, disease, diet, exercise, life style modification, providing materials that motivate patients to achieve a target goal.

8.11. Future studies

Based on the findings and discussion in this study, there is a considerable burden of uncontrolled and poor glycaemic control in Libyans with type II diabetes in one of the main diabetes care settings.. Future research should focus on strategies to improve sustainability of effect, collaborative care of patients between physicians and pharmacists, and cost-effectiveness of pharmacist interventions. Furthermore, medication adherence and exercise promotion programmes would help in reducing the magnitude of poor glycaemic control. Further investigation is proposed to consider the viability of interventions addressing self-care issues in Libya, which has its unique culture and values.

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Appendices

Appendix 1: Search strategy for Medline

4/27/2017 Print Search History: EBSCOhost 27/4/2017

EBSCOhost

Medline search.

Thursday, April 27, 2017 5:26:34 AM

#	Query	Limiters/Expanders	Last Run Via	Results
S15	S3 AND S10 Limit to 2011 –	Limiters - Date of Publication: 20110101-20151231; Publication Type: Randomized Controlled Trial Search modes - Boolean/Phrase	Interface - EBSCOhost Research Databases Search Screen - Advanced Search Database - MEDLINE	14
S14	S3 AND S10 Limit to RCT	Limiters - Publication Type: Randomized Controlled Trial Search modes - Boolean/Phrase	Interface - EBSCOhost Research Databases Search Screen - Advanced Search Database - MEDLINE	21
S13	S3 AND S10 Limit to 2011 –	Limiters - Date of Publication: 20110101-20171231 Narrow by Language: - english Search modes - Boolean/Phrase	Interface - EBSCOhost Research Databases Search Screen - Advanced Search Database - MEDLINE	90
S12	S3 AND S10 Limit to English	Narrow by Language: - english Search modes - Boolean/Phrase	Interface - EBSCOhost Research Databases Search Screen - Advanced Search Database - MEDLINE	145
S11	S3 AND S10 Type 2 diabetes AND Community pharmacy	Search modes - Boolean/Phrase	Interface - EBSCOhost Research Databases Search Screen - Advanced Search Database - MEDLINE	150
S10	S6 OR S7 OR S9 Community pharmacy ALL	Search modes - Boolean/Phrase	Interface - EBSCOhost Research Databases Search Screen - Advanced Search Database - MEDLINE	8,461
S9	S5 AND S8	Search modes - Boolean/Phrase	Interface - EBSCOhost Research Databases Search Screen - Advanced Search Database - MEDLINE	6,150
S8	(MH "Pharmacists") OR "pharmacist*"	Search modes - Boolean/Phrase	Interface - EBSCOhost Research Databases	29,496

Appendix 2: Search strategy for Embase

4/27/2017 Exported Print HTML | Embase

Embase

Embase Session Results

No.	Query	Results
#3	#1 AND 'randomized controlled trial'/de AND (2011:py OR 2012:py OR 2013:py OR 2014:py OR 2015:py OR 2016:py)	32
#2	#1 AND 'randomized controlled trial'/de	44
#1	'non insulin dependent diabetes mellitus'/exp OR 'adult onset diabetes' OR 'adult onset diabetes mellitus' OR 'diabetes mellitus type 2' OR 'diabetes mellitus type ii' OR 'diabetes mellitus, maturity onset' OR 'diabetes mellitus non insulin dependent' OR 'diabetes mellitus, non-insulin-dependent' OR 'diabetes mellitus, type 2' OR 'diabetes mellitus, type ii' OR 'diabetes type 2' OR 'diabetes type ii' OR 'diabetes, adult onset' OR 'dm 2' OR 'insulin independent diabetes' OR 'insulin independent diabetes mellitus' OR 'ketosis resistant diabetes mellitus' OR 'maturity onset diabetes' OR 'maturity onset diabetes mellitus' OR 'maturity onset diabetes of the young' OR 'niddm' OR 'non insulin dependent diabetes' OR 'non insulin dependent diabetes mellitus' OR 'noninsulin dependent diabetes' OR 'noninsulin dependent diabetes mellitus' OR 'type 2 diabetes' OR 'type 2 diabetes mellitus' OR 'type ii diabetes' OR 'type 2 diabet*' AND ('pharmacy'/exp OR 'pharmacist'/exp OR 'community pharmacist' OR 'pharmacist' OR 'pharmacist training' OR 'pharmacists' OR 'pharmacists' aides' OR 'community pharmac*') AND ('community'/exp OR 'community' OR 'community organisation' OR 'community organization')	175

ELSEVIER

https://www.embase.com/search/results 1/1

Appendix 3: Search strategy for Cochrane Library

20170505__1007567979116923834.txt

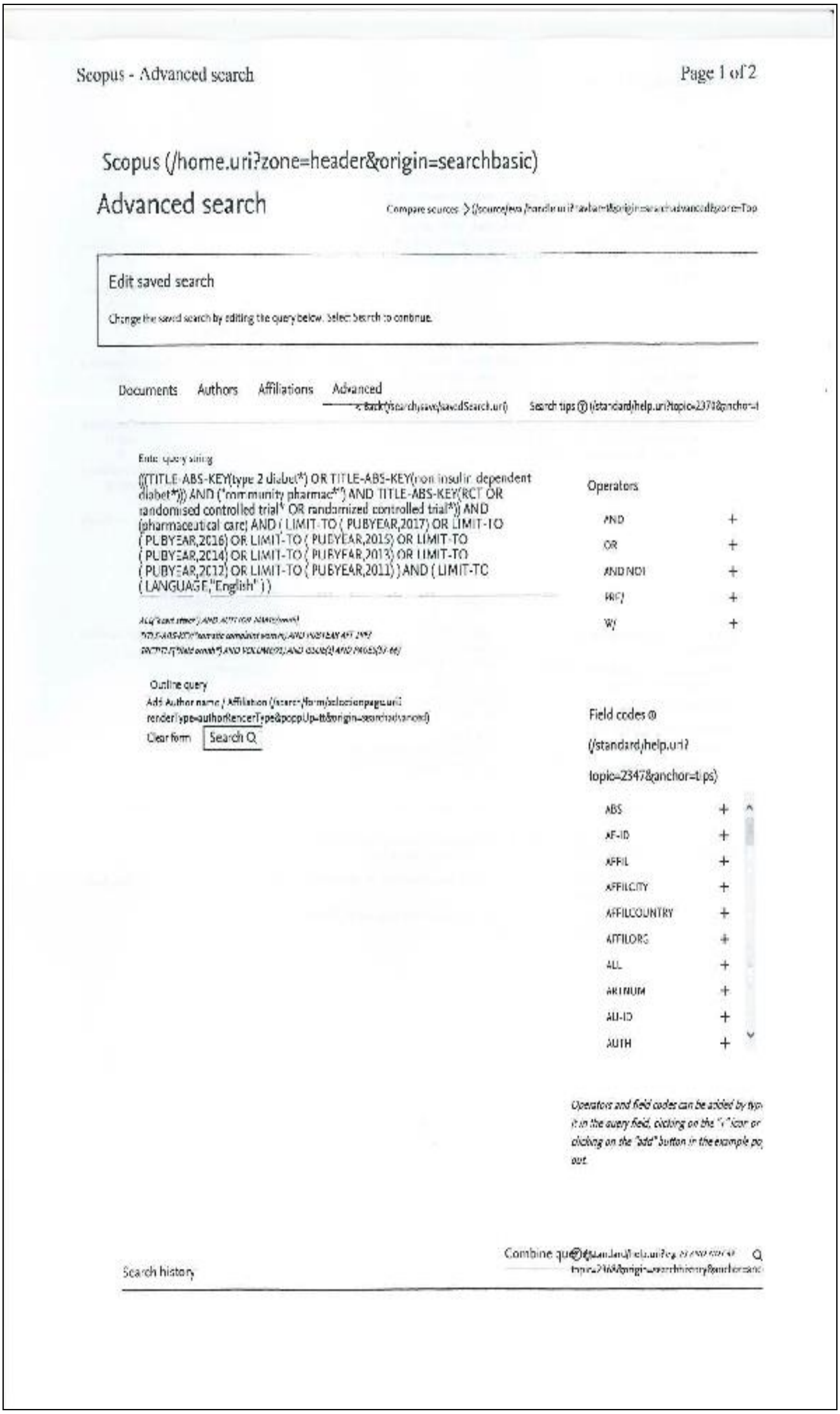
Search Name:
Date Run: 05/05/17 10:57:25.898
Description:

Warning: Problems were found with one or more of your search lines (specific lines are identified below). For best results, you should review and edit the search lines indicated

ID	Search	Hits
[**Error**] ==> #1		
#2	MeSH descriptor: [Diabetes Mellitus, Type 2] explode all trees	11398
#3	MeSH descriptor: [Community Pharmacy Services] explode all trees	259
#4	community pharmac*	5272
#5	#3 or #4	5272
#6	#5 and #2 Publication Year from 2011 to 2017	41
#7	pharmaceutical care	4511
#8	#6 and #7	11

Page 1

Appendix 4: Search strategy for Scopus



Scopus - Advanced search | Page 1 of 2

Scopus (/home.uri?zone=header&origin=searchbasic)

Advanced search

Compare sources > (/sourcelist...)

Edit saved search

Change the saved search by editing the query below. Select Search to continue.

Documents | Authors | Affiliations | Advanced

< Back (/search/saved/savedSearch.uri) | Search tips (/standard/help.uri?topic=2374&anchor=...)

Enter query string

(((TITLE-ABS-KEY(type 2 diabet*) OR TITLE-ABS-KEY(non insulin dependent diabet*))) AND ("community pharmac*") AND TITLE-ABS-KEY(RCT OR randomised controlled trial* OR randomized controlled trial*")) AND (pharmaceutical care") AND (LIMIT-TO (PUBYEAR,2017) OR LIMIT-TO (PUBYEAR,2016) OR LIMIT-TO (PUBYEAR,2015) OR LIMIT-TO (PUBYEAR,2014) OR LIMIT-TO (PUBYEAR,2013) OR LIMIT-TO (PUBYEAR,2012) OR LIMIT-TO (PUBYEAR,2011)) AND (LIMIT-TO (LANGUAGE,"English"))

Outline query

Add Author name / Affiliation (/search/form/selectionpage.uri?renderType=authorRenderType&popUp=t&origin=searchadvanced)

Clear form | Search

Operators: AND + | OR + | AND NOT + | PRE/ + | W/ +

Field codes (/standard/help.uri?topic=2347&anchor=tips)

ABS + | AF-ID + | AFFIL + | AFFILCITY + | AFFILCOUNTRY + | AFFILORG + | ALL + | ARTNUM + | AU-ID + | AUTH +

Operators and field codes can be added by typing it in the query field, clicking on the "+" icon or clicking on the "add" button in the example pop out.

Search history

Combine qu...

Appendix 5: Search strategy for Web of Science

Web of Science [v.5.24] - Web of Science Core Collection Search History

Page 1 of 1

Web of Science™ | InCites™ | Journal Citation Reports® | Essential Science Indicators℠ | EndNote™ | Sign In | Help | English

WEB OF SCIENCE™

Search | My Tools | Search History | Marked List

Search History: Web of Science™ Core Collection

Set	Results	Save History / Create Alert · Open Saved History	Edit Sets	Combine Sets (AND / OR)	Delete Sets
#12	17	TOPIC: (type 2 diabet* or non insulin dependent diabet*) AND TOPIC: ("community pharmac*" OR (community AND pharmacy) OR (community AND pharmacies) OR (community AND pharmacist*)) AND TOPIC: (RCT OR "random* control* trial*") AND TOPIC: (pharmaceutical care) Refined by: PUBLICATION YEARS: (2015 OR 2011 OR 2012 OR 2016 OR 2013 OR 2014 OR 2017) Indexes=SCI-EXPANDED, SSCI, A&HCI, CPCI-S, CPCI-SSH, ESCI Timespan=All years		☐	☐
#11	20	TOPIC: (type 2 diabet* or non insulin dependent diabet*) AND TOPIC: ("community pharmac*" OR (community AND pharmacy) OR (community AND pharmacies) OR (community AND pharmacist*)) AND TOPIC: (RCT OR "random* control* trial*") AND TOPIC: (pharmaceutical care) Indexes=SCI-EXPANDED, SSCI, A&HCI, CPCI-S, CPCI-SSH, ESCI Timespan=All years	Edit	☐	☐
#10	43	TOPIC: (type 2 diabet* or non insulin dependent diabet*) AND TOPIC: ("community pharmac*" OR (community AND pharmacy) OR (community AND pharmacies) OR (community AND pharmacist*)) AND TOPIC: (RCT OR "random* control* trial*") Indexes=SCI-EXPANDED, SSCI, A&HCI, CPCI-S, CPCI-SSH, ESCI Timespan=All years	Edit	☐	☐
#9	43	TOPIC: (type 2 diabet* or non insulin dependent diabet*) AND TOPIC: ("community pharmac*" OR (community AND pharmacy) OR (community AND pharmacies) OR (community AND pharmacist*)) AND TOPIC: (RCT OR "random* control* trial*") Indexes=SCI-EXPANDED, SSCI, A&HCI, CPCI-S, CPCI-SSH, ESCI Timespan=All years	Edit	☐	☐
#8	32	TOPIC: (type 2 diabet* or non insulin dependent diabet*) AND TOPIC: ("community pharmac*" OR (community AND pharmacy) OR (community AND pharmacies) OR (community AND pharmacist*)) AND TOPIC: (RCT OR "random* control* trial*") Refined by: PUBLICATION YEARS: (2015 OR 2011 OR 2016 OR 2012 OR 2014 OR 2013 OR 2017) Indexes=SCI-EXPANDED, SSCI, A&HCI, CPCI-S, CPCI-SSH, ESCI Timespan=All years		☐	☐
#7	48	TOPIC: (type 2 diabet* or non insulin dependent diabet*) AND TOPIC: ("community pharmac*" OR (community AND pharmacy) OR (community AND pharmacies) OR (community AND pharmacist*)) AND TOPIC: (RCT OR "random* control* trial*") Indexes=SCI-EXPANDED, SSCI, A&HCI, CPCI-S, CPCI-SSH, ESCI Timespan=All years	Edit	☐	☐
#6	183	TOPIC: (type 2 diabet* or non insulin dependent diabet*) AND TOPIC: ("community pharmac*" OR (community AND pharmacy) OR (community AND pharmacies) OR (community AND pharmacist*)) Indexes=SCI-EXPANDED, SSCI, A&HCI, CPCI-S, CPCI-SSH, ESCI Timespan=All years	Edit	☐	☐
#5	32	TOPIC: (type 2 diabet* or non insulin dependent diabet*) Refined by: TOPIC: ("community pharmac*") AND TOPIC: (rct OR "random* control* trial*") Indexes=SCI-EXPANDED, SSCI, A&HCI, CPCI-S, CPCI-SSH, ESCI Timespan=All years		☐	☐
#4	131	TOPIC: (type 2 diabet* or non insulin dependent diabet*) Refined by: TOPIC: ("community pharmac*") Indexes=SCI-EXPANDED, SSCI, A&HCI, CPCI-S, CPCI-SSH, ESCI Timespan=All years		☐	☐
#3	160,615	TOPIC: (type 2 diabet* or non insulin dependent diabet*) Indexes=SCI-EXPANDED, SSCI, A&HCI, CPCI-S, CPCI-SSH, ESCI Timespan=All years	Edit	☐	☐
#2	285	TOPIC: (type 2 diabet*) Refined by: TOPIC: (community pharmac*) Indexes=SCI-EXPANDED, SSCI, A&HCI, CPCI-S, CPCI-SSH, ESCI Timespan=All years		☐	☐
#1	168,303	TOPIC: (type 2 diabet*) Indexes=SCI-EXPANDED, SSCI, A&HCI, CPCI-S, CPCI-SSH, ESCI Timespan=All years	Edit	☐	☐
				AND / OR Combine	Select All × Delete

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Appendix 6: Details of risk bias judgement

Random Sequence Generation

Author	Risk rank	Description or (support for judgment)
Ali et al., 2012	Low	(computer generated randomised list)
Jahangard-Rafsanjani et al., 2015	Low	Randomisation sequence was generated based on block randomisation algorithm (1:1 allocation ratio; block size :4)
Venkatesan et al., 2012	Unclear	Just written that 39 patients allocated randomly to 19 in control and 20 to intervention group without any description kind of randomisation
Mehuys et al., 2011	Low	Randomisation table generated using SPSS 14.0 software
Ganawar et al., 2014	Unclear	The method of randomisation unclear. I addition, the number of people in control or intervention group after randomised not mentioned
Kraemer et al., 2012	Unclear	Just state that patient randomly assigned to control or intervention (no description method of randomisation)
Paulo et al., 2016	Low	The randomisation process was performed using a random number table
Kjeldsen et al., 2015	Unclear	No clear description of method randomisation

Allocation concealment

Authors	Risk rank	Support for judgement
Ali et al., 2012	High	The randomisation held by the researcher at the school of pharmacy). The question here was it independent or what? The risk might be high or unclear!
Jahangard-Rafsanjani et al., 2015	Low	2 authors who were not involved in the recruitment process had access to the randomisation list
Venkatesan et al., 2012	Unclear	No description
Mehuys et al., 2011	High	The sequence of allocation to control or intervention group was predetermined by the investigators
Ganawar et al., 2014	Unclear	Not mentioned or no description
Kraemer et al., 2012	Unclear	No description
Paulo et al., 2016	High	The principal investigator who was a pharmacist received the reporting of laboratory test results containing that number and then a constant number on the random table was assigned. The even numbers assigned to intervention group and odd numbers assigned to control group.
Kjeldsen et al., 2015	Unclear	No description

Selective reporting

Authors	Risk rank	Support for judgement
Ali et al., 2012	Low	All the primary outcomes: BMI, BP, BG, HBA1C, LDL, HDL, Total cholesterol and triglycerides reported. The secondary outcomes: DQOL, SIMs, PMQ, Heath status and DKT being reported
Jahangard-Rafsanjani et al., 2015	Low	All primary: HbA1c and secondary outcomes: BP, BMI, Medicine adherence, Diabetes self-care activities reported
Venkatesan et al., 2012	Low	The study outcomes reported in terms of Fasting blood glucose, weight, BMI, diabetes care profile divided into four subscales (Health status, understanding, control problems and social and personal factors) and diabetes knowledge test reported
Mehuys et al., 2011	Low	All the outcomes reported: FPG, HbA1c, medication adherence, DKT and self- care activities in addition to sustainability results of study.
Ganawar et al., 2014	High	Not all of the outcomes reported.
Kraemer et al., 2012	High	Not all of the outcomes reported
Paulo et al., 2016	Low	The primary and secondary outcomes all reported
Kjeldsen et al., 2015	High	Not all of the outcomes reported

Blinding Participants and personnel

Authors	Risk rank	Support for Judgement
Ali et al., 2012	Unclear	Quote: *Patients' general practitioners were informed of their participation, but not to which group the patient had been randomized.*
Jahangard-Rafsanjani et al., 2015	Unclear	Not mentioned
Venkatesan et al., 2012	Unclear	Not mentioned
Mehuys et al., 2011	Unclear	No description
Ganawar et al., 2014	Unclear	No description
Kraemer et al., 2012	Unclear	Quote: *The blinding of study participants was clearly not complete in this study. The research team is aware that employees of one employer talked among themselves and with their human resource manager about the study and thus blinding was doubtful among this subgroup.*
Paulo et al., 2016	High	Single blinded study but not describe who is blinded
Kjeldsen et al., 2015	Unclear	Not described

Blinding outcome assessment

	Risk rank	Support for judgement
Ali et al., 2012	Unclear	No description
Jahangard-Rafsanjani et al., 2015	Unclear	No description
Venkatesan et al., 2012	Unclear	No description
Mehuys et al., 2011	Unclear	No description
Ganawar et al., 2014	Unclear	No description
Kraemer et al., 2012	Unclear	No description
Paulo et al., 2016	Unclear	No description
Kjeldsen et al., 2015	Unclear	No description

Incomplete outcome data

Authours	Risk rank	Support for Judgement
Ali et al., 2012	High	Quote: *Patients' views on their satisfaction with the service were also collected (data not included in this paper).*
Jahangard-Rafsanjani et al., 2015	Low	All outcomes reported
Venkatesan et al., 2012	High	In the demographic information marital status, education and income level not reported
Mehuys et al., 2011	Low	All outcomes reported
Ganawar et al., 2014		Not all of the outcomes reported. In the study mentioned that medication adherence measured by 8 items of self-report Morisky Medication Adherence but is not reported in the study
Kraemer et al., 2012	High	Quote: *Four other parameters (total cholesterol-to-HDL ratio, weight, waist circumference, and body mass index) are not shown due to lack of changes from baseline and differences between groups.*
Paulo et al., 2016	Low	All outcomes reported
Kjeldsen et al., 2015	High	Quote: *Also HbA1c, LDL, HDL, and triglycerides as reported measured by the GP at the most recent visit were collected, but the response rate for these values was below 50% and consequently considered too low for inclusion in the analyses.*

Other sources of bias

	Risk rank	Support for judgement
Ali et al., 2012	Low	
Jahangard-Rafsanjani et al., 2015	Low	
Venkatesan et al., 2012	High	The title of study: Role of community pharmacists in improving knowledge and glycemic control of type 2 diabetes. In the methods of study diabetes care profile assessed based on Fitzgerald of the Michigan Diabetes Research and Training Center (MDRTC) it seems assessing the patients attitudes toward type II diabetes but not mentioned in title (attitudes of psychological and social behaviour)
Mehuys et al., 2011	Low	
Ganawar et al., 2014	Unclear	The descriptive statistics was unclear in terms of demographic data (numbers of male and female in each group control or intervention and all other parameters of study)
Kraemer et al., 2012	Low	
Paulo et al., 2016	Low	
Kjeldsen et al., 2015	Low	

Appendix 7: The pharmacological management of type II diabetes

Key differences	**SIGN**	**LDCG**
Pharmacological management of glycaemic control in people with type II diabetes	• Metformin as first line for overweight patients with type II diabetes. • Pioglitazone can be added to metformin and sulphonylurea therapy, or substituted for either in cases of intolerance. • Pioglitazone should not be used in patients with heart failure. • The risk of fracture should be considered in the long term care of female patients treated with pioglitazone. • Patients prescribed pioglitazone should be made aware of the increased risk of peripheral oedema. • DPP-4 inhibitors may be used to improve blood glucose control in people with type II diabetes. • Alpha-glucosidase inhibitors can be used as monotherapy for the treatment of patients with type II diabetes tolerated.	Step1 – lifestyle intervention and Metformin therapy should be started concurrently with lifestyle intervention at diagnosis. Metformin is recommended as the initial pharmacological therapy, in the absence of specific contraindications (in particular renal impairment), for its effect on glycaemia, absence of weight gain or hypoglycaemia, and relatively low cost. Metformin should be titrated to its maximally effective dose (2000 mg/day or more over 1–3 months, as tolerated). Step2: sulfonylureas and alternatives A sulfonylurea is usually added to metformin, when metformin and lifestyle no longer maintain glucose control to target levels. Hypoglycaemia is sometimes a problem with

	• Oral metformin and sulphonylurea therapy should be continued when insulin therapy is initiated to maintain or improve glycaemic control. • Once daily bedtime NPH insulin should be used when adding insulin to metformin and/or sulphonylurea herapy. Basal insulin analogues should be considered if there are concerns regarding hypoglycaemia risk. When commencing insulin therapy, bedtime basal insulin should be initiated and the dose titrated against morning (fasting) glucose. If the HbA1c level does not reach target then addition of prandial insulin should be considered.	sulfonylureas, and in particular with glibenclamide. Where hypoglycaemia with other sulfonylureas is a problem, a thiazolidinedione or DPP-4 inhibitor are alternatives, as is basal insulin therapy. Sulfonylureas are sometimes used first line where metformin in contraindicated, or for their rapid glucose lowering effect. Step3: basal insulin therapy and alternatives: Basal insulin therapy is highly effective provided proper dose titration and training are provided. It should be added to metformin + sulfonylurea. Risk of hypoglycaemia is a significant issue in many people using insulin education and Self-monitoring should be provided. Alternatives at this stage are a thiazolidinedione or DPP-4

		inhibitor (gliptin), or in the obese a GLP-1 mimetic or acarbose. Step4: multiple insulin therapy In people already on basal insulin therapy, multiple insulin injections including meal-time insulin or by use of pre-mixes may become necessary as islet L-cell failure progresses. Further educational and self-monitoring support should be provided.

Appendix 8: Type II diabetes knowledge and practice awareness among community pharmacist in Tripoli/Libya in pilot stage. Pilot stage

Medicines Management for Patients with Type II Diabetes

Dear Colleague

My name is Nesrin Mohamed Elhatab, I am a PhD student at the University of Bradford in the United Kingdom, supervised by Prof Kay Marshall, Dr Jon Silcock and Dr Steve Britland. I am conducting a research project about Improving Medicines Management for Primary Care Patients with Type II Diabetes in Tripoli, Libya. Your kind response to this questionnaire will be used to guide my research and help to improve medicines management in community pharmacies in Tripoli.

The main aim of my research is to improve medicine management for Libyans with Type II diabetes by enhancing their knowledge, attitudes and self care. This questionnaire (the first part of my project) has the objective of assessing pharmacists' knowledge, attitudes and practice with respect to Type II diabetes.

Your response will be treated in complete confidence. If you wish it can also be anonymous, or you can volunteer to help with the next part of my project. You will not be identified in any reports based on the data collected. All responses will be aggregated as part of the analysis. This questionnaire has been assessed and approved by the research ethics committee at the University of Bradford.

It should take about 15 minutes to complete this questionnaire. Your participation will help me to understand your practice for patients with Type II diabetes. Participation is voluntary, but I would be most grateful for your response.

Please return your questionnaire (whether completed or not) by hand to the person who gave it to you. Please do not hesitate to contact me if you have any questions or you would like a summary of the results.

With kind regards

Nesrin Mohammed Elhatab

Email: nmaelha@student.bradford.ac.uk

Telephone: 0044-7414896689

To be completed by the senior pharmacist

Thank you for your time and cooperation completing questionnaire

Section One: about pharmacy staff and premises

This section includes questions about: level of education; experience of work and training; and the location of your pharmacy.

1. What are your personal qualifications

Level of education	Topic	Institution	Year of graduation

2. How many years have you worked as a community pharmacist?

3. Your gender (please circle)

   a) Male b) Female

4. Have you received any specialised training about diabetes (please circle)

   a) Yes b) No

   If yes, please give details (where, when, what)?

5. Could you provide:

Name of pharmacy	
Area location	
Is that area commercial or residential?	

Optional participation in next stage of project

6. If you would like to volunteer to help with further research, then please give your contact details:

Name	
E-mail address	
Telephone number	

Section Two: availability of type II diabetic medicines and glucose devices measuring

This section includes questions about availability of oral hypoglycaemic medicines and self-monitoring devices in community pharmacies

1. How often are these oral hypoglycemic medicines available in your pharmacy? Please cross (X) to indicate the normal level of availability.

Class of medicine	Generic name	Always	Usually	Sometimes	Rarely	Never
Biguanides	Metformin					
Sulfonylureas	Glibenclamide					
	Glipizide					
	Gliclazide					
Benzoic acid & phenylalanine derived	Repaglindine					
	Nateglindine					
Thiazolidinediones	Rosiglitazone					
	Pioglitazone					
Alphaglucosidase inhibitors	Acarbose					
DDP-4 inhibitors I	Sitagliptin					
GLP-1	Exenatide					
	Liraglutide					

2. How often these glucose measurement devices availability in your pharmacy? Please cross (X) to indicate the normal level of availability.

Devices	Always	Usually	Sometimes	Rarely	Never
Glucose meter					
Glucose meter strips					
Urine dipsticks					

3. How frequently do type II diabetic patients request these glucose measurement devices? Please cross (X) to indicate the normal level of demand.

Devices	Often	Sometimes	Rarely	Never
Glucose meters				
Glucose meter strips				
Urine dipsticks				

Please circle the correct answer in the following questions

4. The correct method for granting a glucometer is to:
   a. use small drop of blood to tell how much glucose is in your blood at that moment
   b. use lots of drops of blood to tell how much glucose is in your blood at that moment
   c. use large drop of blood to tell how much glucose is in your blood at that moment
   d. use three drops of blood to tell how much glucose is in your blood at that moment
5. The normal range of blood glucose pre-prandial in a Type II diabetic patient should be:
   a. 70- 130mg/dl
   b. 100-150 mg/dl
   c. 40-80 mg/dl
   d. 185-200 mg/dl
6. The normal level of blood glucose 2 hours after eating in a Type II diabetic patient should be:
   a) >200mg/dl
   b) <180mg/dl
   c) <70mg/dl
   d) <400mg/dl
7. What should patients do with their blood glucose measurements?
   a) Note them all in a daily diabetes record, and report exceptional values
   b) Note and report the day and time of exceptional values only

Section Three: your workload and professional activities

This section is divided into two parts. Part One relates to caseload (number of patients) and workload (number of visits) in your pharmacy. Part Two concerns the dispensing procedures in your pharmacy.

Part One: caseload and workload

1. Please estimate how many of your regular customers have type II diabetes. (caseload)

____

2. Please estimate how many customers with diabetes visit your pharmacy. (workload)

Daily	Weekly	Monthly	Yearly

3. Please cross (X) in the following table how frequently patients with Type II diabetes visit your pharmacy for the following reasons.

Reason for visits	Often	Sometimes	Rarely	Never
Collect prescriptions				
General consultation about diabetes e.g. diet or general health				
Specific consultation e.g. seeking advice about using OTC medicines				
Interpretation of medical reports				

Part Two: dispensing procedures

4. When dispensing a medicine for a Type II diabetic patients, how frequently do you complete the following actions? Please cross (X) to answer.

Actions	Always	Frequently	Sometimes	Rarely	Never
Review the prescription by finding the generic name.					
Check the prescription is appropriate for the patients' age, weight & sex.					

Check the medicine form, strength, dosage is appropriate.					
Label the package with clear written instructions					
Tell the patient verbally how to use the medicine					
Check the patients' understanding about how take the medicine					
Tell the patient how to store and keep the medicine away from children					
Tell the patient to adhere to the medicine and explain importance					
Give advice about possible side effects					
Advise about possible drug interaction					
Advise about what to do after a missed dose					

Section Four: assessment of your knowledge about diabetes

This section assesses your knowledge and experience of diabetes (please circle responses).

1. Do you have diabetes yourself
   a) Type I b) Type II c) No
2. Do you have family history of diabetes?
   a) Yes b) No
3. Who in your family has diabetes (circle all that apply)
   a) Father or Mother b) Aunt or Uncle
   c) Brother or Sister d) Grandparents
4. The good diabetic diet is:
   b) The way most Libyan people eat b) A healthy diet for most people
   d) Too high in carbohydrate for most people d) Too high in protein for most people
5. Which of the following has the highest fat?
   b) Baked chicken b) Edam chess
   d) Couscous d) Almond
6. Which of the following is highest in fat?
   a) Low fat milk b) Orange juice
   c) Sweet Corn d) Honey
7. Which of the following is a sugar free food?
   e) Any unsweetened food
   f) Any dietetic food (specially made for people with diabetes)
   g) Any food that says “sugar free” on the label
   h) Any food that has less than 20 calories per serving
8. Glycosylated hemoglobin (hemoglobin AI) is a test that is a measure of your average blood glucose level for the past:
   a) Day
   b) Week
   c) 6-10 weeks

d) 6 months

9. Which is the reliable and accurate method for testing blood glucose?
   a) Urine testing
   b) Blood testing
   c) Both are equally good
10. What effect does unsweetened fruit juice have on blood glucose?
   d) Lowers it
   e) Raises it
   f) Has no effect
11. Which should not be used to treat low blood glucose?
   e) 3 hard candies
   f) 1/2 cup orange juice
   g) 1 cup diet coca cola
   h) 1 cup skim milk
12. For a person in good glycaemic control, what effect does exercise have on blood glucose?
   d) Lowers it
   e) Raises it
   f) Has no effect
13. Infection is likely to cause:
   a) An increase in blood glucose
   b) A decrease in blood glucose
   c) No change in blood glucose
14. The best way to take care of your feet is to:
   a) Look at and wash them each day
   b) Massage them with alcohol each day
   c) Soak them for one hour each day
   d) Buy shoes a size larger than usual
15. Eating foods lower in fat decreases your risk for:
   e) Nerve disease
   f) Kidney disease
   g) Heart disease
   h) Eye disease
16. Numbness and tingling may be symptoms of:

a) Kidney disease
b) Nerve disease
c) Eye disease
d) Liver disease

17. Which of the following is usually not associated with diabetes?
    a) Vision problems
    b) Kidney problems
    c) Nerve problems
    d) Lung problems

Thank you for your help.

Appendix 9: Community pharmacist diabetes knowledge and practice toward type II diabetes

Medicines Management for Patients with Type II Diabetes

Dear Colleague

My name is Nesrin Mohamed Elhatab, I am a PhD student at the University of Bradford in the United Kingdom, and supervised by Dr Jon Silcock and Dr Anne Graham I am conducting a research project about Improving Medicines Management for Primary Care Patients with Type II Diabetes in Tripoli, Libya. Your kind response to this questionnaire will be used to guide my research and help to improve medicines management in community pharmacies in Tripoli.

The main aim of my research is to improve medicine management for Libyans with Type II diabetes by enhancing their knowledge, attitudes and self-care. This questionnaire (the first part of my project) has the objective of assessing pharmacists' knowledge, attitudes and practice with respect to Type II diabetes.

Your response will be treated in complete confidence. If you wish it can also be anonymous, or you can volunteer to help with the next part of my project. You will not be identified in any reports based on the data collected. All responses will be aggregated as part of the analysis. This questionnaire has been assessed and approved by the research ethics committee at the University of Bradford.

It should take about 15 minutes to complete this questionnaire. Your participation will help me to understand your practice for patients with Type II diabetes. Participation is voluntary, but I would be most grateful for your response.

Please return your questionnaire (whether completed or not) by hand to the person who gave it to you. Please do not hesitate to contact me if you have any questions or you would like a summary of the results.

With kind regards

Nesrin Mohammed Elhatab

Email: nmaelhat@student.bradford.ac.uk

Mohamed.nesrin@yhaoo.com

To be completed by the senior pharmacist

Thank you for your time and cooperation completing questionnaire

Section One: about pharmacy staff and premises

This section includes questions about: level of education; experience of work and training; and the location of your pharmacy.

13. What are your personal qualifications

Level of education	Topic	Institution	Year of graduation

14. How many years have you worked as a community pharmacist?

---

15. Your gender (please circle)

b) Male b) Female

16. Have you received any specialised training about diabetes (please circle)

b) Yes b) No

If yes, please give details (where, when, what)?

---

17. Could you provide:

Name of pharmacy	
Area location	
Is that area commercial or residential?	

Optional participation in next stage of project

18. If you would like to volunteer to help with further research, then please give your contact details:

Name	

E-mail address	
Telephone number	

Section Two: Counselling practice

19. How often do you offer these types of advice for patients with type II diabetes:

Actions	Always	Frequently	Sometimes	Rarely	Never
How to use medicines					

Continue………………

What medicine is for?					
Special storage instructions					
When to use medicines					
Foods/drinks to avoid					
Special instructions					
Side effects to expect					
How the medicine is likely to affect their condition (that is, its benefits)					
Offer patients information about medicines before the medicines are prescribed					
Check that patients have any information they wish about medicines when the medicines are					

dispensed					
Discuss information on medicines with the patient rather than just presenting it					

20. Highlight the strongest (5) and weakness (1) recommendation provided by Scottish Intercollegiate Guidelines Network (SIGN) about Oral Hypoglycaemic Medicine (OHGM)

Recommendation	Recommendation rank				
	1	2	3	4	5
Metformin should be considered as the first line oral treatment option for overweight patients with type II diabetes.					
Sulphonylureas should be considered as first line oral agents in patients who are not overweight, who are intolerant of, or have contraindications to, metformin.					
Pioglitazone can be added to metformin and sulphonylurea therapy, or substituted for either in cases of intolerance.					
Pioglitazone should not be used in patients with heart failure.					
The risk of fracture should be considered in the long					

term care of female patients treated with pioglitazone.					
Patients prescribed pioglitazone should be made aware of the increased risk of peripheral oedema.					

21. Rates theses reasons (1 low, 5 high) for not providing patient counselling:

Reason	1	2	3	4	5
Lack of pharmacist's time					
Lack of patient's interest					
Lack of patient's time					
Lack of support staff					
Lack of knowledge/training					
Lack of self-confidence					
Lack of pharmacist' interest					

Section Three: assessment of your knowledge about diabetes

This section assesses your knowledge and experience of diabetes (please circle responses). This section divided into three parts: part one about history of diabetes, part two background knowledge of diabetes and part three practical knowledge of diabetes

Part One: History of diabetes

22. Do you have diabetes yourself

    b) Type I b) Type II c) No

23. Do you have family history of diabetes?

    b) Yes b) No

24. Who in your family has diabetes (circle all that apply)

a) Father or Mother b) Aunt or Uncle

c) Brother or Sister d) Grandparents

Part Two: Background knowledge of diabetes (circle the correct answer)

25. The correct method for granting a glucometer is to:
    a) use small drop of blood to tell how much glucose is in your blood at that moment
    b) use lots of drops of blood to tell how much glucose is in your blood at that moment
    c) use large drop of blood to tell how much glucose is in your blood at that moment
    d) use three drops of blood to tell how much glucose is in your blood at that moment
26. The normal range of blood glucose pre-prandial in a Type II diabetic patient should be:
    a) 70- 130mg/dl
    b) 100-150 mg/dl
    c) 40-80 mg/dl
    d) 185-200 mg/dl
27. The normal level of blood glucose 2 hours after eating in a Type II diabetic patient should be:
    e) >200mg/dl
    f) <180mg/dl
    g) <70mg/dl
    h) <400mg/dl
28. What should patients do with their blood glucose measurements?
    c) Note them all in a daily diabetes record, and report exceptional values

d) Note and report the day and time of exceptional values only

29. The good diabetic diet is:

c) The way most Libyan people eat b) A healthy diet for most people

e) Too high in carbohydrate for most people d) Too high in protein for most people

30. Which of the following is highest in carbohydrate?

c) Baked chicken b) Edam chess

e) Couscous d) Almond

31. Which of the following is highest in fat?

a) Low fat milk b) Orange juice

c) Sweet Corn d) Honey

32. Which of the following is a sugar free food?

i) Any unsweetened food

j) Any dietetic food (specially made for people with diabetes)

k) Any food that says “sugar free” on the label

l) Any food that has less than 20 calories per serving

33. Glycosylated hemoglobin (hemoglobin Al) is a test that is a measure of your average blood glucose level for the past:

e) Day

f) Week

g) 6-10 weeks

h) 6 months

34. Which is the reliable and accurate method for testing blood glucose?

d) Urine testing

e) Blood testing

f) Both are equally good

35. What effect does unsweetened fruit juice have on blood glucose?

g) Lowers it

h) Raises it

i) Has no effect

36. Which should not be used to treat low blood glucose?

i) 3 hard candies

j) 1/2 cup orange juice

k) 1 cup diet coca cola

l) 1 cup skim milk

37. For a person in good glycaemic control, what effect does exercise have on blood glucose?

g) Lowers it

h) Raises it

i) Has no effect

38. Infection is likely to cause:

d) An increase in blood glucose

e) A decrease in blood glucose

f) No change in blood glucose

39. The best way to take care of your feet is to:

e) Look at and wash them each day

f) Massage them with alcohol each day

g) Soak them for one hour each day

h) Buy shoes a size larger than usual

40. Eating foods lower in fat decreases your risk for:

i) Nerve disease

j) Kidney disease

k) Heart disease

l) Eye disease

41. Numbness and tingling may be symptoms of:

e) Kidney disease

f) Nerve disease

g) Eye disease

h) Liver disease

42. Which of the following is usually not associated with diabetes?

e) Vision problems

f) Kidney problems

g) Nerve problems

h) Lung problems

Part Three: Practical knowledge of diabetes

43. Diabetes is a condition that:

Please circle ONE answer only

a) Can be cured by adopting a healthy lifestyle
b) Can be cured with tablets and/or insulin
c) Is currently not curable
d) Is always life threatening when first diagnosed
e) Unsure

44. Which of the following statements about diabetes and diet is true?
Please circle ONE answer only
f) People with diabetes should eat a sugar free diet
g) It is OK to eat fried take away food three times a week
h) Red meat is a carbohydrate food
i) A diet which is low in fat, high in fibre, low in added sugar is recommended for everyone with diabetes
j) Unsure

45. Why are people with diabetes advised to test their own blood glucose (BG)?
Please circle ONE option only
a) To alert them to changes in BG level patterns
b) To help make decisions in relation to exercise, treating ‘hypos’ (low BG) or sick-day management.
c) It can make people more confident in looking after their diabetes
d) All of the above

46. What should a person with diabetes do if s/he becomes ill (e.g. flu, gastric upset, infection)?
Please circle AS MANY as apply, or circle ‘Unsure’.
a) Check blood glucose level more frequently (every 2 to 4 hours)
b) Stop taking all diabetes tablets and/or insulin.
c) Drink lots of non-sweet fluid if blood glucose levels are over 15mmol/L
d) Seek medical attention if very unwell and unable to check blood glucose
e) Try to do as much exercise as possible to lower blood glucose levels
f) Unsure

47. What foot problems are people with diabetes most at risk of?
Please circle AS MANY as apply, or circle ‘Unsure’
a) Poor circulation

b) Loss of feeling in the feet
c) Foot ulcers
d) Hammer to Infections
e) Unsure

48. How often should people with diabetes exercise or be physically active?
Please circle ONE answer only

f) Most days of the week for at least 30 minutes
g) Once a week for at least 30 minutes
h) Once a month for one hour
i) At least every fortnight for two hours
j) Unsure

49. Why is doing regular exercise or being physically active good for your health?
Please circle AS MANY as apply, or circle 'Unsure'

g) It can help to control blood glucose levels
h) It can lower blood pressure
i) It can help to regulate a person's mood
j) It can reduce the risk of skin cancer
k) It can lower cholesterol levels
l) Unsure

50. If a person with diabetes has a hypo (low blood glucose level) reaction, s/he should: Please circle ONE answer only

f) Immediately take some insulin or diabetes tablets
g) Rest and wait until s/he feels better
h) Immediately have some sugary food or drink (e.g. jelly beans, soft drink)
i) Drink some diet soft drink
j) Unsure

51. Well-managed diabetes decreases the risk of:
Please circle AS MANY as apply, or circle 'Unsure'

a) Kidney damage
b) Blindness
c) Melanoma
d) Heart disease

e) Foot ulcers

f) Unsure

52. People with diabetes need a medical check-up of their eyes, nerve and kidney function at least: Please circle ONE answer only

a) Every month

b) Six monthly

c) Once a year

d) Every two to three years

e) Unsure

53. Which of the following statements about diabetes medication is true? Please circle ONE answer only

a) If blood glucose levels are normal for two months, diabetes medication can be stopped.

b) Tablets for diabetes work by increasing blood glucose levels

c) Regular medical check-ups are necessary to assess the need for adjustments to diabetes medication.

d) People taking diabetes medication do not need to worry about healthy eating

e) Unsure

Comments: could you please provide us with any comments it could help us and many thanks for your response.

Appendix 10: Detailed comparison between MDKT and ADKQ

Items	MDKT	ADKT	Comment
1) Diet management	• The diabetes diet is: a. the way most American people eat b. a healthy diet for most people* c. too high in carbohydrate for most people d. too high in protein for most people • Which of the following is highest in carbohydrate? a. Baked chicken b. Swiss cheese c. Baked potato* d. Peanut butter • Which of the following is	Which of the following statements about diabetes and diet is true? Please circle ONE answer only a. People with diabetes should eat a sugar free diet b. It is OK to eat fried take away food three times a week c. Red meat is a carbohydrate food d. A diet which is low in fat, high in fibre, low in added sugar is recommended for everyone with diabetes e. Unsure	MKDT highlights the importance of diet management and uses five items to cover a healthy diet: low in carbohydrate, low in fat, low in sugar, and why fatty food should be avoided. But in ADKT one item used to define healthy diet in a simple way.

	highest in fat? a. Low fat milk* b. Orange juice c. Corn d. Honey • Which of the following is a "free food"? a. Any unsweetened food b. Any dietetic food c. Any food that says "sugar free" on the label d. Any food that has less than 20 calories per serving* • Eating foods lower in fat decreases your risk for: a. nerve disease b. kidney disease		

	c. heart disease* d. eye disease		
2) Blood glucose measurement management	Glycosylated haemoglobin (hemoglobin Al) is a test that is a measure of your average blood glucose level for the past: a. day b. week c. 6-10 weeks* d. 6 months	A blood test called HbA1c (or A1c) measures the average blood glucose levels over the past 2 to 3months. What is the HbA1c result that indicates a lowest risk of developing long-term diabetes complications? Please circle ONE answer only a. Less than or equal to 7% b. Less than 8% c. 9% d. Less than or equal to 10% e. Unsure	MDKT focus on the measurement of GbA1c. ADKT focus on the importance of test why it is done. Both questions are very important for knowledge assessment
3) Impact of infection on blood glucose	Infection is likely to cause: a. an increase in blood glucose* b. a decrease in blood glucose c. no change in blood glucose	What should a person with diabetes do if s/he becomes ill (e.g. flu, gastric upset, infection)? Please circle AS MANY as apply, or circle 'Unsure' a. Check blood glucose level more frequently (every	In MDKT the focus was on the cause of infection (when people are infected what happens to blood glucose). However, in ADKT the focus of the question is what the patient does when ill. MDKT tests the knowledge about consequences of infection. Whilst

		2 to 4 hours) b. Stop taking all diabetes tablets and/or insulin c. Drink lots of non-sweet fluid if blood glucose levels are over 15mmol/L d. Seek medical attention if very unwell and unable to check blood glucose e. Try to do as much exercise as possible to lower blood glucose levels f. Unsure	ADKTQ tests the knowledge of management of diabetes after infection. Both aspects of knowledge are fundamental and important.
4) Foot care management	• The best way to take care of your feet is to: a. look at and wash them each day* b. massage them with alcohol each day c. soak them for one hour each day	What foot problems are people with diabetes most at risk of? Please circle AS MANY as apply, or circle 'Unsure' a. Poor circulation b. Loss of feeling in the feet c. Foot ulcers d. Hammer toe e. Infections	MDKT focus on the knowledge of foot care and also test the knowledge of nerve disease symptoms. However, ADKT focus on the consequences or causes or complications of foot disease (neuropathy). It is very important to understand how to avoid foot disease and also the mechanism of

	d. buy shoes a size larger than usual • Numbness and tingling may be symptoms of: a. kidney disease b. nerve disease* c. eye disease d. liver disease	f. Unsure	disease.
5) Exercise management	For a person in good control, what effect does exercise have on blood glucose? a. Lowers it* b. Raises it c. Has no effect	How often should people with diabetes exercise or be physically active? Please circle ONE answer only a. Most days of the week for at least 30 minutes b. Once a week for at least 30 minutes c. Once a month for one hour d. At least every fortnight for two hours e. Unsure	MDKT tests knowledge about exercise impact on blood glucose. ADKT highlights frequency of exercise recommended and also the benefits and impact of exercise on your health more precisely.

		• Why is doing regular exercise or being physically active good for your health? Please circle AS MANY as apply, or circle 'Unsure' a. It can help to control blood glucose levels b. It can lower blood pressure c. It can help to regulate a person's mood d. It can reduce the risk of skin cancer e. It can lower cholesterol levels f. Unsure	
6) Blood glucose management	Which is the best method for testing blood glucose? a. Urine testing b. Blood testing* c. Both are equally good	Why are people with diabetes advised to test their own blood glucose (BG)? Please circle ONE option only a. To alert them to changes in BG level patterns b. To help make decisions in relation to exercise, treating	MDKT focus on the knowledge of blood glucose analysis. ADKT gives the reader more knowledge about the importance of blood glucose monitoring.

		'hypos' (low BG) or sick-day management c. It can make people more confident in looking after their diabetes d. All of the above	
7) Complication of diabetes understanding	Which of the following is usually not associated with diabetes: a. vision problems b. kidney problems c. nerve problems d. lung problems*	Well-managed diabetes decreases the risk of: Please circle AS MANY as apply, or circle 'Unsure' a. Kidney damage b. Blindness c. Melanoma d. Heart disease e. Foot ulcers f. Unsure	MDKT tests the respondents understanding about diabetes complications. However, ADKT highlights the benefit of good diabetes management in diabetic patients' health and address the complication of diabetes.
8) Hypoglycaemic management	Which should not be used to treat low blood glucose? a. 3 hard candies b. 1/2 cup orange juice c. 1 cup diet soft drink* d. 1 cup skim milk	If a person with diabetes has a hypo (low blood glucose level) reaction, s/he should: Please circle ONE answer only a. Immediately take some insulin or diabetes tablets b. Rest and wait until s/he feels better	Both MDKT and ADKT mention the importance of sugary drinks, but MDKT highlights the sweet drink that should be avoided when treating hypoglycaemia. ADKT tests knowledge in a more general way.

		c. Immediately have some sugary food or drink (e.g. jelly beans, soft drink) d. Drink some diet soft drink e. Unsure	
9) Check-up management		People with diabetes need a medical check-up of their eyes, nerve and kidney function at least: Please circle ONE answer only a. Every month b. Six monthly c. Once a year d. Every two to three years e. Unsure	
10) Diabetes medication knowledge		Which of the following statements about diabetes medication is true? Please circle ONE answer only a. If blood glucose levels are normal for two months, diabetes medication can be stopped	

		b. Tablets for diabetes work by increasing blood glucose levels c. Regular medical check-ups are necessary to assess the need for adjustments to diabetes medication d. People taking diabetes medication do not need to worry about healthy eating e. Unsure	
11) Facts about diabetes		Diabetes is a condition that: Please circle ONE answer only a. Can be cured by adopting a healthy lifestyle b. Can be cured with tablets and/or insulin c. Is currently not curable d. Is always life threatening when first diagnosed e. Unsure	

Appendix 11: Community pharmacy premises survey in Tripoli/Libya.

UNIVERSITY of BRADFORD

Community pharmacy premises questionnaire in Tripoli/ Libya

The study aims to find out the structure of community pharmacies in Tripoli. Your participation is voluntary and the data will be analyses anonymous and confidential.

Premises details

Q1 Please enter the premises details below:

Name of pharmacy	
Area location	
Name of street	
Type of pharmacy: private or public	
The pharmacy located in commercial or residential?	
Number of staff work in the pharmacy	
Number of community pharmacist in the pharmacy	
Number of pharmacist technician work in the pharmacy	

Opening hours

Q2 Could you please write the opening hours and closed

Day	**Open from**	**To**
Saturday		
Sunday		
Monday		
Tuesday		
Wednesday		

Thursday		
Friday		

Consultation facilities

Presence of Consultation area:

Q3 Do you have consolation area in your pharmacy?

- Yes
- No

Q4 If yes, could you tell about it?

Is the consultation area located?

- On premises
- Off premises

Q5 During consultations are there hand washing facilities?

- No hand washing facilities
- Hand washing facilities in consulting room
- Hand washing facilities close to consulting room

Q6 Do patients attending for consultations have access to toilet facilities?

- Yes
- No

Pharmaceutical Services

Essential services :

Q7 Does the pharmacy dispense appliances?

- Yes
- No

Q8 If yes, what type of appliances does the pharmacy dispense?

- All types

- All excluding stoma appliances
- All excluding incontinence appliances
- All excluding stoma and incontinence appliances
- Just dressings
- Other please specify

Q9 Does the pharmacy provide repeat dispensing services for diabetic medicine?

- Yes
- No

Q10 If yes, what is the average monthly number of repeat dispensing clients?

- 0-10
- 11-20
- 21-30
- 31-40
- Over 40

Q11 Do you dispose unwanted medicines?

- Yes
- No

Q12 Do you dispose unwanted glucometer strips?

- Yes
- No

Advanced Services

Q12 Does the pharmacy provide the following services?

Diabetes medicine management	**Yes**	**No**
Glucometer use review service	Yes	No

Q13 Could you please select the diabetes medicine management that you provide?

- ◯ Patient education
- ◯ Initial assessment and monitoring:
- ◯ Check height, weight and calculate BMI;
- ◯ Check smoking status
- ◯ Glucose Control
- ◯ Dietary advice
- ◯ Referral
- ◯ Management of glucose control

Enhanced services

Q14 Which of the following services does the pharmacy provide, or would be willing to provide?

Disease specific medicines management service	**Not providing**	**Willing to provide in the future**	**Providing**
Allergies			
Alzheimer's/ dementia			
Depression			
Diabetes type I			
Diabetes type II			
Epilepsy			
Heart failure			
Hypertension			
Parkinson's disease			

Thank you for your cooperation

Appendix 12: Educational material about type II diabetes sent to community pharmacists

Type II diabetes education

Section one: Introduction

When the body does not produce enough insulin or does not use it properly, type II diabetes (or insulin resistance diabetes) develops. Type II diabetes is most often diagnosed in overweight adults over the age of 40 with a family history of diabetes. However, type II diabetes is becoming increasingly common in younger people, especially adolescents. Certain racial and ethnic groups, are more prone to developing diabetes in their lifetime. Often, type II symptoms develop gradually, so people may have the disease for months or even years before it is diagnosed. Most people who develop type II diabetes first exhibit signs of pre-diabetes, with blood glucose levels elevated but below the diabetes range.

Insulin is the gatekeeper of the body that assures that blood glucose, or blood sugar, is handled properly. When the response to insulin in the body is ineffective, glucose builds up in the blood and accumulates. As diabetes develops, other health problems, such as high blood pressure and high cholesterol are also likely to occur. Recent research on obesity in children also indicates there is an increased risk of hybrid or double diabetes. People with type I diabetes who become overweight and have high blood pressure are at risk of developing type II as well.

What Happens When You Have Diabetes?

With type II diabetes, a number of systems may be functioning poorly. It takes 5-10 years for type II diabetes to develop. It is a slow progression of the following issues:

Your pancreas, particularly the beta cells, is not able to make enough insulin to control blood glucose levels. Your fasting blood glucose slowly creeps up over the years (pre-diabetes) until the insulin can no longer keep the levels in check and diabetes is diagnosed.

Insulin resistance is also a factor; the body resists the normal functioning of the insulin because of chronic inflammation related to excess weight and inactivity. There then is an increased demand for more insulin since it is less effective. This is called impaired glucose tolerance.

Hepatic glucose output—the liver, with its storage bank of glucose, begins to release more glucose than it needs to. The result is fasting blood glucose rises.

With type I diabetes, there is an autoimmune disease action that destroys the beta cells of the pancreas. These cells make insulin, so that the body no longer has a mechanism to lower blood glucose effectively. People with type I diabetes must take exogenous insulin (from outside the body) to stay alive.

In order to stay healthy by managing your diabetes well, you have a number of tools to help. Diet, exercise and medications are your arsenal of control. But first, you need to know your numbers by testing your blood sugar.

Questions Newly Diagnosed Type II Diabetes Patients Might Ask

Why Me?

Genes and environment play a role in whether a person gets diabetes or not. Diabetes is not your fault. You have done nothing to cause it to happen; but what you can do now is learn how to take control of your health as best you can. At first, you may not really believe the diagnosis—and you may bargain with the doctor for a few more months so you can lose some weight or start exercising. Denial is common, but when reality sets in, you may feel the anger of being burdened with a disease. Anger may turn to feeling overwhelmed, or depressed. These feelings are natural coping mechanisms. You will come to a stable point, where you will be open to learning how to manage your health and diabetes. With knowledge and a positive attitude, you can lead a long, high-quality life.

There Must Be Some Mistake?

The lab results could be repeated, for your peace of mind. There are very definitive standards for the diagnosis; it is not a judgment call by your doctor. A fasting blood test of 126mg/dl or higher on two occasions, or HgA1c test of 6.5 percent or higher.

What Went Wrong?

You may have certain higher risks for developing type II diabetes, some of which are genetic. If you have a parent or sibling with diabetes, are over the age of 45, and of Arabic Libyan parents, you are at higher risk genetically. A female is at higher risk if she has had gestational diabetes or a baby over nine pounds at delivery. Additional risk factors are: being overweight, waist circumference higher than 35 inches in women, 40 inches in a man; high cholesterol; inactivity and if you smoke.

How is Type II Diabetes Treated?

By the time you are diagnosed with diabetes, your pancreas may have lost 50 percent or more of its insulin-producing capability. This may slowly decline overtime. Changes happen over time that determines your treatment plan. The four major changes are:

The body's cells become resistant to the action of insulin

The pancreas first makes more insulin, but then less and less over time

Less insulin is released with meals and blood glucose remains high

The liver isn't releasing glucose correctly

Your treatment plan is based on what changes are happening. You need to work on your food intake and physical activity, and may also need an oral medication. (The first medication that is typically prescribed is metformin for type II diabetes.) You may need additional oral medications as time passes. You may eventually need insulin injections or other injectable medications. You may have a different "mix" of diet and medications than another person with diabetes; this depends on your unique body. You may also need blood pressure medication and blood fat medication as part of your prevention plan.

What Can I Eat?

A nutrition plan for a person with diabetes is a healthy diet that has less than 50 percent of calories from carbohydrates. Carbohydrates should be selected from three major food groups:

Starches: preferably high fiber, grains, cereals, breads, pasta, rice, legumes, starchy vegetables like potatoes, and peas

Fruits

Low fat diary such as milk and yogurt

Added sugar is not recommended, but a person with diabetes who has well-controlled blood glucose can work small amounts of sugar into their diet. The major selection of food needs to be lean proteins such as tuna and vegetables. The diet should be low in saturated fats, to prevent heart disease. Use of olive oil is preferred. Eat three balanced meals a day at regular times, select the healthiest foods, and achieve or maintain your healthiest possible weight.

Do I Have to Give Up Sugar?

A simple directive you may have heard is: "people with diabetes can't have sugar." But this is not true! What is true is that many people do consume too much simple sugar in sodas, sweetened teas, fruit juice, other sweetened beverages, candy, and desserts. These foods do not have a regular place in a diabetes friendly diet, especially if this person needs to lose weight. Simple sugars raise blood glucose levels quickly and quite high, so are not helpful to controlling blood glucose. A small amount of sugar however, when eaten with a meal, will have a lesser impact on blood glucose. The total amount of carbohydrates eaten at a meal, and for the entire day, is more important in managing blood glucose levels.

Can Diabetes Be Cured?

To date, there is no cure for type II diabetes. However, when some people lose weight, exercise more often, and improve their nutrition, their blood glucose returns to normal without the need for medication. Some persons with diabetes who have had bariatric surgery eliminate their need for medication to manage blood glucose. However, even with lower blood glucose and diminished symptoms, the disease is still present.

Do I Have to Test My Blood?

Self-monitoring blood glucose is an important tool in controlling your diabetes. Your doctor will instruct you how often and when to test your blood glucose, as well as your target goals pre and post meals. You may need to improve your dietary or exercise habits to manage your numbers to an optimum range.

What Should My Blood Glucose Numbers be?

Your fasting blood glucose, as well as before a meal, should be 80mg/dl to 130mg/dl. Two hours after a meal, no higher than 180mg/dl. Before bed, blood glucose targets range from 110-150 mg/dl.

What is A1c?

A1c is short for Hemoglobin A1c which is a measure of blood glucose that reflects the average blood glucose for the past 60-90 days. A1C is also used to diagnose diabetes. An A1C of 6.5 percent or higher is an indication of diabetes.

Can I Just Take a Pill?

Oral medications are usually an important part of your treatment plan, but first lifestyle changes may be recommended. Weight loss if necessary, increased exercise and controlling carbohydrate intake are important ways to manage your diabetes without medication. These recommendations may be the first prescribed step by your doctor. Lifestyle changes may reduce the need for oral medication, and provide better blood glucose control with medication.

Do I Have to Take Insulin?

Diabetes is a progressive disease, and there may be a point in time when lifestyle changes and oral medications aren't enough to give good glycemic control. Trust your doctor's clinical judgment in making the right decision for your diabetes treatment. Many people who feared using insulin find they feel better and have better control over their disease. People with type I diabetes must take insulin because their pancreas produces none.

What Happens if My Blood Sugar Goes Too Low?

Low blood sugar or hypoglycemia is a blood glucose below 70 mg/dl which occurs when someone takes blood sugar lowering medicine and doesn't eat, or exercises too much, or delays or skips a meal. Symptoms are light-headedness, shakiness, sweating, blurred vision and labored speech, confusion and could lead to unconsciousness.

What happens if My Blood Sugar stays too high?

Hyperglycemia is before meal blood glucose over 130 mg/dl and over 180 mg/dl 2 hours after meals. If blood glucose is occasionally high but not over 250 mg/dl, you may not have any symptoms. Symptoms to watch for are extreme thirst, frequent urination and hunger. Even without symptoms, the elevated concentration of glucose in your blood is damaging tissues. Unchecked high blood sugars will eventually lead to serious conditions including seizures, unconsciousness and coma. If your blood glucose levels are high, be sure to avoid dehydration by drinking adequate fluids.

Do I Have To Exercise?

Think of it as increasing your physical activity. Moving more will lower your blood sugar, help you control your weight and improve your fitness level. It is a part of the recommended treatment plan for nearly every person, especially those with diabetes.

Who Can Help Me With This?

Expect to be more connected to your primary care physician, and maybe an endocrinologist who specializes in diabetes care.

How Do I Prepare for Sudden Illness?

This is a good topic for your doctor to discuss with you. If you have been sick for 24 hours and your blood sugars are high, call your doctor. If you have ketones in your urine, call your doctor. Avoid dehydration by drinking plenty of fluids, and keep track of the medications you take. You will want to review which cold relief medications are safe for you to take when you are under the weather. Keep a record of your blood glucose to show the doctor.

Section two: newly diagnosed person with type 2 diabetes

11 Essential Things You Must Do (As a Newly Diagnosed Person with Type II Diabetes)

1. Test Your Blood Glucose

Your doctor will give you a glucometer and test strips and have a nurse show you what to do, so you can demonstrate enough knowledge to test blood glucose yourself. The strips and meters should not be left in any places where extreme hot or cold temperatures could occur, like a car. Be sure the test strips are coded with the meter and not expired.

2. Control Your Carbohydrates

Carbohydrates are converted to glucose by digestion. Insulin carries the blood glucose into the cells to provide energy for living. If the insulin is lacking or ineffective, the glucose piles up in the blood, causing problems for the body. Limiting carbohydrates to a level that the insulin can manage is one treatment of diabetes. Carbohydrates are sugar, fruit, lactose in milk and yogurt, and starches such as grains, bread, salted biscuits, macaroni or spaghetti, rice, legumes such as humus and beans, and starchy vegetables such as potatoes, potatoes, zucchini, peas and corn. Your dietitian or certified diabetes educator can plan an individualized carbohydrate plan for you. Typically, women consume 45 grams of carbs per meal, and men 60 grams per meal. Keep snacks to 25-30 grams of carbohydrate.

3. Get Moving

Exercise lowers blood glucose. This is a second treatment for high blood glucose. Physical activity is important for everyone, even those without diabetes. It will improve your mood, help with weight loss, build muscle, strengthen bones, and improve your sleep. Try to get 30 minutes of exercise most days. Be sure to check your blood glucose before you exercise. If it is lower than 90 mg/dl, eat a light snack, and if higher than 250 mg/dl, do not exercise until within a more normal range.

4. Become Educated and Know Your Numbers

What are your target blood glucose goals? Your doctor may give you individual instruction, but these are the American Diabetes Association recommendations:

Fasting and before meals: 70-130 mg/dl

2 hours after start of a meal: 180 mg/dl

A1C: <7%(tested every 3 months or more)

5. Build Your Support Team

Your team should consist of your doctor or an endocrinologist, a certified diabetes educator, a registered dietitian, a foot doctor (podiatrist), a dentist, an eye doctor and an exercise professional.

6. Take Your Medicine as Directed (and know how it works)

Diabetes is a progressive disease and there may come a point where diet and exercise, called lifestyle changes, aren't enough to keep your glucose under control. There are quite a few oral medications that help lower blood glucose in different ways. Be sure you understand how to take the medication, what side effects to watch for, and how the medications work. There are also injectable medicines, and insulin by injection that are very effective in managing blood glucose.

7. Know How to Treat Low Blood Sugar

The signs of hypoglycemia are shakiness, sweating, weakness, blurred vision, hunger. A quick ingestion of simple carbohydrate is necessary to bring your blood sugar back up.

8. Lose Weight

Most people with type II diabetes start out overweight-above their ideal body weight. Weight loss, of even just 10 percent, can make a huge difference in blood glucose levels. Some people see their blood glucose go back to normal with lifestyle changes alone.

9. Get an Annual Physical with Blood Work to Prevent Complications

There are large and small vessel problems that might occur over time, so make it a habit to get a good check-up annually. Your eyes, kidneys, nervous system, heart, skin, teeth and feet are all susceptible to injury from diabetes and high blood glucose.

10. Know What to Do If You are Sick?

Talk with your doctor about sick day plans. Call your doctor If you have been having vomiting or diarrhea for 6 hours, your blood sugars are over 240 mg/dl for 24 hours even with medicine, and if you show ketones in your urine. Remember to stay well hydrated.

11. Watch Your Blood Pressure and Cholesterol

Diabetes is closely related to heart disease. You need to control your blood pressure within 120/80 mmHg to reduce stress on blood vessels and kidneys. Protect your heart by lowering your LDL cholesterol <100mg/dl, and triglycerides <150 mg/dl and HDL cholesterol men >40 mg/dl and women >50 mg/dl. You may be prescribed prophylactic statins and blood pressure medicine to reduce your risk of complications.

The Rule of 15

Hypoglycemia, or low blood sugar, is when blood glucose levels drop below 70 mg/dl. Symptoms are shakiness or trembling, sweating, weakness, fatigue, dizzy or light headedness, headache, hunger, blurred vision or altered speech, nausea, rapid heartbeat. Severe symptoms may progress to confusion, seizures or unconsciousness.

Why does this happen? Taking too much diabetes medication, delaying or skipping a meal, too few carbohydrates at a meal, increased exercise can all cause hypoglycemia.

How to treat Using the Rule of 15

Take your blood glucose. If it is 70 mg/dl or below, consume 15 grams of easy to digest carbohydrate such as: 1/2 cup fruit juice; 1/2 cup regular soda; five-six hard candies; or three sugar packets

Wait 15 minutes to feel better

Check your blood glucose again, and if still low, take 15 grams of carbohydrate

When your blood glucose starts to go up, wait about an hour and recheck. Eat a hearty snack or your next meal

Special Note

Resist the urge to over-treat. Don't drink unlimited amounts of sugared drinks to get your blood glucose up, it may go too high and may take days to get it regulated.

Alert

If three attempts don't work to bring your blood glucose up, call for emergency

Section three: Your Diabetes Emergency Plan

Prepare diabetes emergency kit in which you can keep critical information and supplies in case of an emergency. A kit you can grab in a hurry with all you need to take care of your medical health. Choose a container that is insulated, waterproof and portable.

Information for Your Kit:

Your type of diabetes

List of all your medications

Contact information of your doctors and Certified Diabetes Educator, as well as family members

Most recent lab results

Letter from your healthcare providers describing your medication and food regimen. If you are on insulin, your current insulin to carbohydrate ratio and correction factor, or typical dosing routine.

Kit Supplies:

A supply of all your oral and injectable medications

If on insulin, a glycogen kit, as well as glucose tablets or gels to treat low blood glucose. Also, some juice boxes, candy or sugar packets

Blood glucose testing supplies and extra batteries

Empty plastic bottle for safe disposal of sharps

Non-perishable food supply such as, raisins, nuts such as almonds, dates and unsalted biscuits.

Bottled water

First aid kit with bandages, band-aides, cotton swabs, antibiotic ointments

Money for unexpected cash-only needs

Extra set of clothes and undergarments, socks; mini bottles of toothpaste, shampoo, etc.

Prepaid cell phone and important numbers

Section four: The Diabetic Diet - Your Choice

Diabetic Plate Diet

The Food Pyramid has been replaced with the Plate Method Diet by the UDSA and Department of Health and Human Services to describe a healthy diet for Americans (www.choosemyplate.gov). The Plate Method can be adapted for people with diabetes who want a simple, easy guideline on how to eat. With this visual tool, you can control your food portions and spread the carbohydrate evenly within each meal and throughout the day.

Using a 9 inch plate, divide it into 4 quarters for both lunch and dinner. Fill the plate like this:

1/2 plate with non-starchy vegetables (cauliflower, green bean, leafy greens, salad, carrots, etc)

1/4 plate with starches (bread, rice, spaghetti, legumes, grains, cereal, cuscus, starchy vegetables like potatoes, pumpkin, zucchini, , peas and legumes)

1/4 plate with meat (lean beef, lamb, camel, fish, ricotta, eggs, cheese)

one cup low fat milk (on the side)

One serving of fruit. (on the side) (one piece fresh, 1/2 cup unsweetened canned)

The breakfast plate will be arranged a little differently:

1/4 to 1/2 plate with starch

1/4 plate with protein

One serving of milk and one serving of fruit.

Although a simplistic tool to plan your meals, be careful about preparation methods and added condiments like butter and salad dressings, which can add extra calories.

Exchange List for Diabetic Meal Planning

The Exchange List was created by the American Dietetic Association and the American Diabetic Association to provide a consistent approach to calculating a diabetic meal plan. Foods are divided into six groups (each group has common nutrient composition): Milk, Meats, Starch, Fruit, Vegetables, and Fats. A meal plan is created by defining a set number of servings from each group. The advantage of this approach is better calorie control, and manipulation of the nutritional quality of the diet.

Sample 1,500 Calorie Diet Using Food Exchanges

Meal	Exchange	Food& amount	Carb count (grams)
Breakfast	1 meat	1 scrambled egg	0
	1 starch	1 slice toast	15
	1 milk	1 cup skim milk	12 (round - up to 15)
	1fruit	1 peach	15
	1 fat	1 tsp. margarine on toast	0
		Total	45 grams
Lunch	2 meats	2 oz. chicken	0
	2 starch	2 slices whole wheat bread	30
	1 milk	low fat yogurt (no sugar added)	15

Carbohydrate Counting

Carbohydrate counting is a third option for better management of diabetes. The focus is to eat a prescribed number of carbohydrates at meals and snacks. A typical plan might be 45 grams of carbs at each meal, and one snack with 15 grams of carbs. This totals 150 grams of carbohydrates per day. For people with type II diabetes, the carb counting can be learned from the exchange lists. A serving, or choice, of starch, fruit, or milk group provides 15 grams of carbs. Once someone learns portion sizes, carbohydate counting makes estimating a meal's carbohydrate content quick and simple. People with type I diabetes, who are on insulin, or even the insulin pump, must be exact about their carbohydrate counting since their insulin dose is based on the amount they eat at a meal. Advanced carbohydrate counting calculates for the smaller amounts of carbohydrate throughout all food choices, and may use such tools as carbohydrate listing booklets or online apps that track food intake. The disadvantage with only using the carbohydrate counting method is that other nutrients aren’t monitored and calorie intake is not controlled

Section five: What You Need to Know about Diabetes and Medications?

Insulin shots used to be the only treatment for diabetes for years. Insulin is a protein, and if swallowed would be digested. Therefore, it must be administered by injection. Scientists have been working to find oral medications to help control diabetes. There are many to choose from today, and each category of medication does something different to help manage the blood glucose. If you are on a medication, learn about how it works, be sure you take it when and how you should, and be alert to side effects.

Each drug belongs to a class, and each class of drugs works in specific ways. Some work on the pancreas, increasing its output of insulin. Another class works on the liver, decreasing the amount of sugar it releases. Another class works on the muscle, making it more sensitive to insulin. Even the GI tract (gastrointestinal) can be altered to decrease the absorption of carbohydrates and increase helpful hormones called GLP-1.

Some people may be on several oral medications, or oral and injectable. Some medications are also in combination pills. Injectable and insulin are now available in easy to use pens, with extremely tiny needles. Insulin is also used in insulin pumps. You need to check your blood glucose regularly to know how effective your medication, exercise and diet are keeping your blood glucose in range. You can make corrections if you know what is happening to your blood glucose.

The charts below give you an overview of all the types of medications that can be of help.

Medications for Type II Diabetes

Classification	Medication	Route	How it Works
Sulfonylureas	Glimepiride (Amaryl) Glipizide (Glucotrol) Glyburide	Oral	Increases insulin production by the pancreas
Biguanides	Metformin	Oral	Lowers glucose released by the liver
Alpha-Glucosidases Inhibitors	Miglitol (Glyset)	Oral	Slows digestion, slows glucose production

	Acarbose (Precose)		
Thiazolodinediones	Pioglitizone (Actos)	Oral	Reduces insulin resitance, works in muscles and liver
Meglitinides	Repaglinide (Prandin) Nateglinide (Starlix)	Oral	Increases insulin production by pancreas
DPP-4 Inhibitors	Stagliptin (Januvia) Saxagliptin (Onglyza) Lingliptin (Tradjenta)	Oral	Lowers glucose by blocking an enzyme in the intestine
GLP-1 Incretin Mimetics	Liraglutide (Victoza) Extenatide (Byetta) Bydureon	Injectable	Helps the pancreas make insulin. Decreases glucagon to reduce glucose
Amylin Analog	Pramlintide (Symlin)	Injectable	Controls after meal blood glucose; used with insulin

Commonly Used Insulin

Types of Insulin	Onset of Action	Peak	Duration
Fast-Acting:			
Regular	1/2-1 hour	2-4 hours	6-8 hours
Humolog, Novolog, Apidra	<15 minutes	1-2 hours	4-6 hours
Intermediate-Acting:			
NPH	1-2 hours	6-10 hours	12+ hours
U-500 Regular	30 minutes	2-4 hours	5-7 hours
Lantus	1.5 hours	Flat, maximun effect 5 hours	24-hour
Levemir	1-hour	Flat, maximum effect 5 hours	12-24 hours

Appendix 13: Diabetes Knowledge Test

UNIVERSITY of BRADFORD

How Much Do You Know About Diabetes Care?

1. The correct method for granting a glucometer is to:
   e) use small drop of blood to tell how much glucose is in your blood at that moment
   f) use lots of drops of blood to tell how much glucose is in your blood at that moment
   g) use large drop of blood to tell how much glucose is in your blood at that moment
   h) use three drops of blood to tell how much glucose is in your blood at that moment
2. The normal range of blood glucose pre-prandial in a Type II diabetic patient should be:
   e) 70- 130mg/dl
   f) 100-150 mg/dl
   g) 40-80 mg/dl
   h) 185-200 mg/dl
3. The normal level of blood glucose 2 hours after eating in a Type II diabetic patient should be:

i) >200mg/dl

j) <180mg/dl

k) <70mg/dl

l) <400mg/dl

4. What should patients do with their blood glucose measurements?

e) Note them all in a daily diabetes record, and report exceptional values

f) Note and report the day and time of exceptional values only

5. The good diabetic diet is:

d) The way most Libyan people eat b) A healthy diet for most people

f) Too high in carbohydrate for most people d) Too high in protein for most people

6. Which of the following is highest in carbohydrate?

d) Baked chicken b) Edam chess

f) Couscous d) Almond

7. Which of the following food is a major carbohydrate source?

- A. Spinach
- B. Apple
- C. Egg
- D. Cheese

8. Which of the following is highest in fat?

a) Low fat milk b) Orange juice

c) Sweet Corn d) Honey

9. Which of the following is a sugar free food?

m) Any unsweetened food

n) Any dietetic food (specially made for people with diabetes)

o) Any food that says “sugar free” on the label

p) Any food that has less than 20 calories per serving

10. What is the best meal plan for people with diabetes?

- A. Balanced diet--like the Plate Diet
- B. Low in carbohydrate choices only
- C. High protein diet
- D. Not sure

11. Glycosylated hemoglobin (hemoglobin Al) is a test that is a measure of your average blood glucose level for the past:

i) Day

j) Week

k) 6-10 weeks

l) 6 months

12. Which is the reliable and accurate method for testing blood glucose?

g) Urine testing

h) Blood testing

i) Both are equally good

13. What effect does unsweetened fruit juice have on blood glucose?

j) Lowers it

k) Raises it

l) Has no effect

14. Which should not be used to treat low blood glucose?

m) 3 hard candies

n) 1/2 cup orange juice

o) 1 cup diet coca cola

p) 1 cup skim milk

15. For a person in good glycaemic control, what effect does exercise have on blood glucose?

j) Lowers it

k) Raises it

l) Has no effect

16. Infection is likely to cause:

g) An increase in blood glucose

h) A decrease in blood glucose

i) No change in blood glucose

17. The best way to take care of your feet is to:

i) Look at and wash them each day

j) Massage them with alcohol each day

k) Soak them for one hour each day

l) Buy shoes a size larger than usual

18. Eating foods lower in fat decreases your risk for:

m) Nerve disease

n) Kidney disease

o) Heart disease

p) Eye disease

19. Numbness and tingling may be symptoms of:

i) Kidney disease

j) Nerve disease

k) Eye disease

l) Liver disease

20. Which of the following is usually not associated with diabetes?

i) Vision problems

j) Kidney problems
k) Nerve problems
l) Lung problems

21. Diabetes is a condition that:

Please circle ONE answer only

f) Can be cured by adopting a healthy lifestyle
g) Can be cured with tablets and/or insulin
h) Is currently not curable
i) Is always life threatening when first diagnosed
j) Unsure

22. Which of the following statements about diabetes and diet is true?

Please circle ONE answer only

k) People with diabetes should eat a sugar free diet
l) It is OK to eat fried take away food three times a week
m) Red meat is a carbohydrate food
n) A diet which is low in fat, high in fibre, low in added sugar is recommended for everyone with diabetes
o) Unsure

23. Why are people with diabetes advised to test their own blood glucose (BG)?

Please circle ONE option only

e) To alert them to changes in BG level patterns
f) To help make decisions in relation to exercise, treating ‘hypos’ (low BG) or sick-day management.
g) It can make people more confident in looking after their diabetes
h) All of the above

24. What should a person with diabetes do if s/he becomes ill (e.g. flu, gastric upset, infection)?

Please circle AS MANY as apply, or circle ‘Unsure’.

g) Check blood glucose level more frequently (every 2 to 4 hours)
h) Stop taking all diabetes tablets and/or insulin.
i) Drink lots of non-sweet fluid if blood glucose levels are over 15mmol/L

j) Seek medical attention if very unwell and unable to check blood glucose

k) Try to do as much exercise as possible to lower blood glucose levels

l) Unsure

25. What foot problems are people with diabetes most at risk of?

Please circle AS MANY as apply, or circle 'Unsure'

f) Poor circulation

g) Loss of feeling in the feet

h) Foot ulcers

i) Hammer toes

j) Infections

k) Unsure

26. How often should people with diabetes exercise or be physically active?

Please circle ONE answer only

k) Most days of the week for at least 30 minutes

l) Once a week for at least 30 minutes

m) Once a month for one hour

n) At least every fortnight for two hours

o) Unsure

27. Why is doing regular exercise or being physically active good for your health?

Please circle AS MANY as apply, or circle 'Unsure'

m) It can help to control blood glucose levels

n) It can lower blood pressure

o) It can help to regulate a person's mood

p) It can reduce the risk of skin cancer

q) It can lower cholesterol levels

r) Unsure

28. If a person with diabetes has a hypo (low blood glucose level) reaction, s/he should: Please circle ONE answer only

k) Immediately take some insulin or diabetes tablets

l) Rest and wait until s/he feels better

m) Immediately have some sugary food or drink (e.g. jelly beans, soft drink)

n) Drink some diet soft drink

o) Unsure

29. Well-managed diabetes decreases the risk of:

Please circle AS MANY as apply, or circle ‘Unsure’

g) Kidney damage

h) Blindness

i) Melanoma

j) Heart disease

k) Foot ulcers

l) Unsure

30. People with diabetes need a medical check-up of their eyes, nerve and kidney function at least: Please circle ONE answer only

f) Every month

g) Six monthly

h) Once a year

i) Every two to three years

j) Unsure

31. Which of the following statements about diabetes medication is true?

Please circle ONE answer only

f) If blood glucose levels are normal for two months, diabetes medication can be stopped.

g) Tablets for diabetes work by increasing blood glucose levels

h) Regular medical check-ups are necessary to assess the need for adjustments to diabetes medication.

i) People taking diabetes medication do not need to worry about healthy eating.

j) Unsure.

Appendix 14: Protocol of study

Medicine management for type II diabetic patients in Tripoli

The prevalence of diabetes is growing dramatically these days due to different reasons such as ageing and increasing of obese people. To void long term complication diabetes requires more medical care and on-going patient self - management education. The American Diabetes Association stated (2012, p.1) ‘Diabetes care is complex and requires that many issues, beyond glycemic control, be addressed’. Diabetes care requires diabetes team means there are many people engaging to help diabetic persons to live and manage the disease effectively. It is very important that health care provider do not impose on the person but negotiate with them, so they can fit their diabetes management into their everyday life (Living with diabetes, 2006). The effectiveness of community pharmacist intervention in the management of type II diabetes has been supported and studied (Mehuys et al., 2011; Almazroui et al., 2009; Lidenmeyer et al., 2006; Wermeille et al., 2004).

The current study focuses on two aspects of diabetes management: self-management (i.e. how people manage everyday life in terms of diet, exercise, feet care, eye care) and medicine management (i.e. oral hypoglycaemic adherence). In the long term, diabetes cannot be managed by medicine or diet alone when first diagnosed type II diabetes can be managed by diet and exercise. However, older people have to take oral hypoglycaemic tablets to control blood glucose levels, and may progress to management with insulin.

To manage diabetes successfully, patients must be able to set goals and make frequent daily decisions that are both effective and fit their values and lifestyles, while taking into account multiple physiological and personal psychosocial factors. Intervention strategies that enable patients to make decisions about goals, therapeutic options, and self-care behaviours and to assume responsibility for daily diabetes care are effective in helping patients care for themselves (Funnel& Anderson, 2004).There are some identified essential elements of diabetes self-management that people with diabetes need to be able to access, and a minimum service level that needs to be in place to ensure that people are supported to self-manage. The necessary elements of diabetes self-management are highlighted in Figure 2.1(Diabetes UK, 2009).

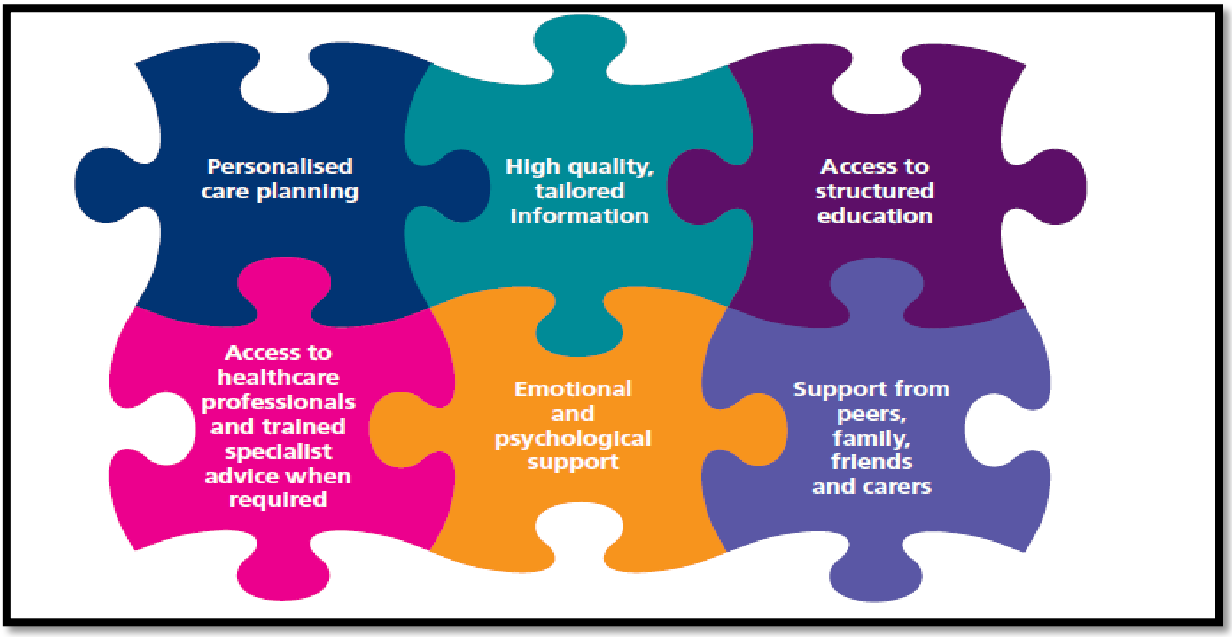

Figure 1.1: Essential elements of diabetes self-management

Source: Diabetes UK (2009)

There are a number of potential barriers to self-management. Physical barriers include the nature of their medical condition(s) where people have different needs. System barriers include conflicting advice, or a lack of collaborative working, between healthcare and social care professionals in providing services and on-going support for self-management. The structure of 'once a year only' reviews also works against self-management, as people can benefit from seeing their healthcare professionals on a more regular basis. This barrier is considered one of the most common. Financial barriers include physical limitations of access to services, time and locations, financial cost, local availability of services and on-going support once people have had self-management training or guidance. Another potential barrier is resistance to change on the part of healthcare professionals, many of whom have been traditionally trained to deliver care to their patients; different skills are needed to effectively support people living with long-term conditions such as diabetes.

Research Aim and Objectives

The main aim of this research is centred on improving diabetes medicine management amongst Type II diabetic Libyan patients through the use of self-completion questionnaires and semi-structured interviews, and finally randomised controlled trials. The study will take six months in order to assess glycaemic control. In order to achieve this aim, the following objectives have been set:

1. To assess pharmacists' knowledge, attitudes and practices towards diabetes care in community pharmacies within Libya.
2. To assess Type II diabetic patients' awareness and attitudes.
3. To determine the barriers of diabetes medicine management amongst pharmacists and Type II diabetic patients in Tripoli, Libya
4. To provide patients with the diabetic information required, and to revise health checks by community pharmacist.

Methodology:

The research is divided into four stages. The first stage aims to explore community pharmacists' knowledge, attitudes and practices towards Type II diabetes care. The reason for completing an audit for pharmacists' diabetes knowledge and practices is to gain understanding into the weaknesses and strengths. Stage One is recognised as a descriptive stage; therefore, the study can be seen as using combined methods: a literature review and self-completion questionnaire in order to generate the relevant data that can both inform and provide a clear picture regarding the current situation of the study problem. The second stage will investigate Type II medicine management barriers of diabetes care amongst patients. During this stage, I sought to understand the barriers amongst community pharmacists and Type II diabetic patients in regard to implementing medicines management. The second stage will utilise a semi-structured interview and literature review. The third stage explores Type II diabetes knowledge, attitudes and practices toward diabetes care through the use of a self-completion questionnaire. The reason for doing this is in order to investigate the various elements of weak diabetes knowledge. The fourth stage will adopt a randomised controlled trial or non-randomised control trial to improve Type II diabetes disease and medicine management.

Once understanding has been gained in regard to Type II diabetes knowledge and practices, as well as the barriers facing community pharmacists and patients from implementing medicine management, the decision will be made as to which study should be used in order to complete such an intervention so as to improve diabetes medicine management.

Cluster randomisation:

It may be preferable, for reasons of cost or feasibility, to randomise the clusters containing individuals rather than individuals themselves.

Reasons for Adopting Cluster Randomization:

- Administrative convenience
- To obtain cooperation of investigators
- Ethical considerations
- To enhance subject compliance
- To avoid treatment group contamination
- Intervention naturally applied at the cluster level.

The opinion is widely held that RCTs provide high-evidence grade whilst observational studies are considered less valid due to reported overestimate treatment effects. This view ignores the disadvantages of randomised controlled trials. There are many limitations of RCTs, such as they are somewhat pointless, unsuitable and impossible or insufficient. Furthermore, it is sometimes difficult to implement because of professional resistance, and there is also difficulty in terms of gaining ethical consent, as well as political and legal obstacles (Black, 1996).

The effectiveness of community pharmacists' intervention on the medicine and disease management of Type II diabetes has been studied in Belgium by Mehuyset al. (2008, 2011). Accordingly, I aim to replicate the Belgium study and to compare the outcomes in the two locations. It is also expected that the differences in lifestyle and culture will have a significant impact. Accordingly, the question is posed as to whether or not the randomised controlled trails are effective on Type II diabetes management in Libya? Using RCTs in the future study is not done in order to test new medicines but simply to reorganise patient care by asking them about various factors, namely medicine adherence and lifestyle, management, reviewing foot and eye checks the patients requires, and asking them to gather readings of fasting plasma glucose. The aim of using RCTs in the final stage is to assess the level of effectiveness of community pharmacists compared with Belgium study. Importantly, this provides a rationale for why an intervention study cannot be carried out before an audit for Type II diabetes knowledge and practices, and understanding of the barriers, is conducted.

Protocol of patient study: there are two stages in this study.

First stage: Type II Diabetic Patients' Recruitment

The patients are going to be recruited through community pharmacies. Community pharmacists are going to provide eligible patients with a patient questionnaire, including personnel information, knowledge, and attitudes towards diabetes, beliefs, and self-management.

Aim and Objectives

The aim is to explore patients' diabetes knowledge and self-management; this will be achieved through setting the following objectives:

1. To assess patients' diabetes knowledge and practices through the use of the Australian Diabetes Knowledge Test (Eigenmann et al (2011).
2. To assess patient diabetes self-management through the adoption of the Summary of Diabetes Self-Care (Toobert et al., 2000).

Second stage: Intervention by Community Pharmacists

This phase is referred to as intervention by community pharmacists in order to improve Type II diabetic patient management, as well as to improve cooperation between pharmacists and patients on the basis that community pharmacists are easily accessible. Customers visit community pharmacies without any appointment, and so the pharmacist needs to be able to help and work together with the patient in order to achieve improvement. Before the start of the study, the intervention pharmacists will be provided with educational materials about the pathophysiology of Type II diabetes and its non-pharmacological and pharmacological management according to current treatment guidelines, as well as the study protocol. The control pharmacists only received training on the study protocol.

Aims and Objectives

The aim is to improve Type II diabetes management by measuring blood glucose control and to enhance pharmacists' knowledge and practices towards diabetes care. In order to achieve the aim, the following objectives need to be completed:

1. To provide patients with a diabetes record on which their fasting plasma glucose can be detailed.

Methods

1. A comparison between two groups (control and intervention)
2. The provision of usual pharmacist care to patients in the control group
3. Patients in the intervention group are to receive a protocol-defined intervention at the start of the study and at each prescription-refill visit (for hypoglycaemic medication) during the course of the study
4. The intervention design was based on Stage One of the Belgium study (Mehuys et al., 2008), and comprised several elements, namely:
    - Education about Type 2 diabetes and its complications;
    - Education about the correct use of oral hypoglycaemic agents (timing in relation to food);
    - The facilitation of medication adherence (by counselling);
    - Healthy lifestyle education (diet, physical exercise and smoking cessation); and
    - Reminders about annual eye and foot examinations.

Factors Influencing Loss of Precision Cluster Randomization Trials

- Interventions often applied on a group basis with little or no attention given to individual study participants.
- Some studies permit the immigration of new subjects after baseline.
- Entire clusters, rather than just individuals, may be lost to follow-up
- Presence of experimental contamination.
- Over-optimistic expectations regarding effect size

- Difficulties associated with prevention trials (low event rates, compliance problems, and incomplete exposure to intervention).

How the cluster randomisation to be done?

To improve the precision of data collected the pharmacies going to divide into two groups control and intervention. So, the researcher just knows which pharmacies are control and intervention to avoid study bias. Then each group provide with three types of questionnaire attached in the appendix I, II, III and glucometer record sheet of FBG. In addition to other materials such as meeting sheet, some diabetes education materials, and diabetes patient leaflet.

What about ethical consideration?

Nothing without ethics, each patient participates in the study going to provide him/her by patient information sheet (Appendix IV) and consent form (Appendix V).

Appendix 15: Type II diabetes awareness questionnaire English version

Type II Diabetes Awareness Questionnaire

Dear Participant

I am a PhD student studying at University of Bradford in UK. I am doing research about diabetes care in Tripoli/Libya. The aim of the study is to improve glucose control in type II diabetes by understanding your knowledge, attitudes and self-management.

I am delighted if you participate in this study. Your response will be treated in complete confidence. If you wish it can also be anonymous. You will not be identified in any reports based on the data collected. All responses will be aggregated as part of the analysis. This questionnaire has been assessed and approved by the research ethics committee at the University of Bradford.

It should take about 10 minutes to complete this questionnaire. Your answers will help us to suggest ways to improve your care. Participation is voluntary.

Please return your questionnaire (whether completed or not) by hand to the pharmacist who gave it to you. Please do not hesitate to contact me if you have any questions or you would like a summary of the results.

Telephone number: 0044-7414896689

Email address: nmaelhat@student.bradford.ac.uk

We truly appreciate your help! Thank you!

Section One: Demographic Data

1. Could you please tell me your date of birth?

………../……………………/……………………………

2. Are you

☐ Male ☐ Female

3. How long have you had diabetes?

……..................years ....months or

…........days.

4. What type of diabetes do you have?

☐ Type I ☐ Type II o☐

Unsure

5. How would you describe the amount of verbal information you receive about your diabetes when you were first diagnosed? (please tick one box only)

☐ I did not receive any verbal information

☐ I received too little verbal information

☐ I received about the right amount of verbal information

☐ I received too much verbal information

☐ I did not want any verbal information

☐ I do not know, a career was given verbal information

☐ I cannot remember

6. How would you describe the amount of written information you received about your diabetes when you were first diagnosed? (please tick one box only)

☐ I did not receive any written information

☐ I received too little written information

☐ I received about the right amount of written information

☐ I received too much written information

☐ I did not want any written information

☐ I do not know, a career was given written information for me

☐ I cannot remember

7. Do you take diabetes medication? ☐ Yes ☐ No

If yes……………………. glucose lowering tablets

And/or .... Dietary and exercise control

8. If ticked glucose lowering tablets, how many different tablets?

☐ 1 ☐ 2 ☐ 3

Other, please specify ....

9. Have you ever seen a diabetes educator?

☐ Yes ☐ No

10. Have you ever seen a dietician?

☐ Yes ☐ No

Optional participation:

11. If you would like to volunteer to help with further research, then please give your contact details:

Name	
E-mail address	
Telephone number	

Section Two: Diabetes Knowledge Test

This section assesses your knowledge and experience of diabetes (please circle responses).

1. Diabetes is a condition that:

Please circle ONE answer only

a. Can be cured by adopting a healthy lifestyle
b. Can be cured with tablets and/or insulin
c. Is currently not curable
d. Is always life threatening when first diagnosed
e. Unsure

2. Which of the following statements about diabetes and diet is true?

Please circle ONE answer only

a. People with diabetes should eat a sugar free diet
b. It is OK to eat fried take away food three times a week
c. Red meat is a carbohydrate food
d. A diet which is low in fat, high in fibre, low in added sugar is recommended for everyone with diabetes

e. Unsure

3. Why are people with diabetes advised to test their own blood glucose (BG)? Please circle ONE option only

a. To alert them to changes in BG level patterns

b. To help make decisions in relation to exercise, treating ‘hypos’ (low BG) or sick-day management.

c. It can make people more confident in looking after their diabetes

d. All of the above

4. The correct method for granting a glucometer is to:

e. use small drop of blood to tell how much glucose is in your blood at that moment

f. use lots of drops of blood to tell how much glucose is in your blood at that moment

g. use large drop of blood to tell how much glucose is in your blood at that moment

h. use three drops of blood to tell how much glucose is in your blood at that moment

5. The normal range of blood glucose pre-prandial in a Type II diabetic patient should be:

   e. 70- 130mg/dl
   f. 100-150 mg/dl
   g. 40-80 mg/dl
   h. 185-200 mg/dl

6. The normal level of blood glucose 2 hours after eating in a Type II diabetic patient should be:

   m) >200mg/dl
   n) <180mg/dl
   o) <70mg/dl
   p) <400mg/dl

7. What should patients do with their blood glucose measurements?

   g) Note them all in a daily diabetes record, and report exceptional valuesNote and report the day and time of exceptional values only

8. What should a person with diabetes do if s/he becomes ill (e.g. flu, gastric upset, infection)?

Please circle AS MANY as apply, or circle ‘Unsure’.

a. Check blood glucose level more frequently (every2 to 4 hours)
b. Stop taking all diabetes tablets and/or insulin.
c. Drink lots of non-sweet fluid if blood glucose levels are over 15mmol/L
d. Seek medical attention if very unwell and unable to check blood glucose
e. Try to do as much exercise as possible to lower blood glucose levels
f. Unsure

9. What foot problems are people with diabetes most at risk of?

Please circle AS MANY as apply, or circle ‘Unsure’

a. Poor circulation
b. Loss of feeling in the feet
c. Foot ulcers
d. Hammer to
e. Infections
f. Unsure

10. How often should people with diabetes exercise or be physically active?

Please circle ONE answer only

a. Most days of the week for at least 30 minutes
b. Once a week for at least 30 minutes
c. Once a month for one hour
d. At least every fortnight for two hours
e. Unsure

11. Why is doing regular exercise or being physically active good for your health?

Please circle AS MANY as apply, or circle ‘Unsure’

s) It can help to control blood glucose levels
t) It can lower blood pressure
u) It can help to regulate a person’s mood
v) It can reduce the risk of skin cancer
w) It can lower cholesterol levels
x) Unsure

12. If a person with diabetes has a hypo (low blood glucose level) reaction, s/he should: Please circle ONE answer only

p) Immediately take some insulin or diabetes tablets

q) Rest and wait until s/he feels better
r) Immediately have some sugary food or drink (e.g. jelly beans, soft drink)
s) Drink some diet soft drink
t) Unsure

13. Well-managed diabetes decreases the risk of:
Please circle AS MANY as apply, or circle ‘Unsure’
m) Kidney damage
n) Blindness
o) Melanoma
p) Heart disease
q) Foot ulcers
r) Unsure

14. People with diabetes need a medical check-up of their eyes, nerve and kidney function at least: Please circle ONE answer only
k) Every month
l) Six monthly
m) Once a year
n) Every two to three years
o) Unsure

15. Which of the following statements about diabetes medication is true? Please circle ONE answer only
k) If blood glucose levels are normal for two months, diabetes medication can be stopped.
l) Tablets for diabetes work by increasing blood glucose levels
m) Regular medical check-ups are necessary to assess the need for adjustments to diabetes medication
n) People taking diabetes medication do not need to worry about healthy eating
o) Unsure

Comments

Thank you for your cooperation and help

Appendix 16: Diabetes self-management questionnaire English version

Diabetes Self-Management Questionnaire

The questions below ask about your diabetes self-care activities during the past seven days. If you were sick during the past seven days please think back to the last seven days when you were not sick.

Q1: diet

Diet	Number of days							
On how many of the last seven days have you followed a healthful eating plan?	0	1	2	3	4	5	6	7
On average, over the past month, how many days per week have you followed you're eating plan?	0	1	2	3	4	5	6	7
On how many of the last seven days did you eat five or more servings of fruits and vegetables?	0	1	2	3	4	5	6	7
On how many of the last seven days did you eat high fat foods such as red meat or full-fat dairy products?	0	1	2	3	4	5	6	7
On how many of the last seven days did you space carbohydrates evenly through the day?	0	1	2	3	4	5	6	7

Q2: Exercise

Exercise	Number of days							
On how many of the last seven days did you participate in at least 30 minutes of physical activity?	0	1	2	3	4	5	6	7
On how many of the last seven days did you	0	1	2	3	4	5	6	7

participate in a specific exercise session (such as such swimming, walking, biking) other than what you do around the house or as part of your work?								

Continue……………

Q3: blood sugar testing

Blood Sugar Testing	Number of days							
On how many of the last seven days did you test your blood sugar?	0	1	2	3	4	5	6	7
On how many of the last seven days did you test your blood sugar the number of times recommended by your health care provider?								

Q4: foot care

Foot Care	Number of days							
On how many of the last seven days did you check your feet?	0	1	2	3	4	5	6	7
On how many of the last seven days did you inspect the inside of your shoes?								

Q5: Smoking

a. Have you smoked a cigarette-even one puff-during the past seven days?

☐ No

☐ Yes. If yes, how many cigarettes did you smoke on an average day?

Number of cigarettes ………………..…

b. At your last doctor's visit, did anyone ask about your smoking status?

☐ No

☐ Yes

c. If you smoke. At your last doctor's visit, did anyone counsel you about stopping smoking or offer to refer you to stop-smoking program?

- ☐ No
- ☐ Yes
- ☐ Do not smoke

d. When did you last smoke a cigarette?

- ☐ More than two years ago, or never smoked
- ☐ One to two years ago
- ☐ Four to twelve months ago
- ☐ One to three months ago
- ☐ Within the last month
- ☐ Today

Q6: Self Care Recommendations

a. Which of the following has your health care team (doctor, nurse, dietician, or diabetes educator, pharmacist) advised you to do?

Please check all that apply:

- ☐ Follow a low-fat eating plan
- ☐ Follow a complex carbohydrate diet
- ☐ Reduce the number of calories you eat to lose weight
- ☐ Eat lots of food high in dietary fiber
- ☐ Eat lots (at least 5 servings per day) of fruits and vegetables
- ☐ Eat very few sweets (for example: desserts, non-diet sodas, candy bars)
- ☐ Other (specify):
- ☐ I have not been given any advice about my diet by my health care team.

b. Which of the following has your health care team (doctor, nurse, dietitian or diabetes educator) advised you to do? Please check all that apply:

- ☐ Get low level exercise (such as walking) on a daily basis.
- ☐ Exercise continuously for a least 20 minutes at least 3 times a week.
- ☐ Fit exercise into your daily routine (for example, take stairs instead of
- ☐ elevators, park a block away and walk, etc.)
- ☐ Engage in a specific amount, type, duration and level of exercise.

☐ Other (specify):
……………………………………………………………………………...
☐ I have not been given any advice about exercise by my health care team.

c. Which of the following has your health care team (doctor, nurse, dietitian, or diabetes educator) advised you to do? Please check all that apply:

☐ Test your blood sugar using a drop of blood from your finger and a color chart.

☐ Test your blood sugar using a machine to read the results.

☐ Test your urine for sugar.

☐ Other (specify):

☐ I have not been given any advice either about testing my blood or urine sugar level by my health care team

d. Which of the following medications for your diabetes has your doctor prescribed?

Please check all that apply.

☐ Insulin shot 1 or 2 times a day.

☐ Insulin shot 3 or more times a day.

☐ Diabetes pills to control my blood sugar level.

☐ Other (specify):

☐ I have not been prescribed either insulin or pills for my diabetes.

Appendix 17: Type II diabetes attitudes questionnaire English version

Type II diabetic attitudes questionnaire toward diabetes care

Dear participant

I am a PhD student studying at University of Bradford in the UK. I am doing research about diabetes care in Tripoli/Libya. The aim of the study is to improve glucose control in type II diabetes by understanding your knowledge, attitudes and self-management.

I am doing this research to understand your attitudes toward type II diabetes care. I would be delighted if you took part in the study by kindly completing this questionnaire. Some people ask these questions: How long will this take?

This questionnaire only takes about 5 to 10 minutes to complete

OK, what do I do?

Fill in the questionnaire as quickly and honestly as you can. Hand it back to the pharmacist who gave it to you.

Do I have to take part?

No, of course not. Your participation is completely voluntary. Your answers will help us to suggest ways to improve your care.

Your response will be treated in complete confidence. If you wish it can also be anonymous. You will not be identified in any reports based on the data collected. All responses will be aggregated as part of the analysis. This questionnaire has been assessed and approved by the research ethics committee at the University of Bradford.

We truly appreciate your help! Thank you!

Mrs Nesrin Elhatab

Email address: nmaelhat@student.bradford.ac.uk
Mohamed.nesrin@yahoo.com

Telephone no: 0044-07735095109

Section one: personnel information:

1. What are your personal qualifications

---

2. Your gender (please circle)

c) Male b) Female

3. How old are you?

---

4. How many years have you had diabetes?

---

5. Do you have type II diabetes

☐ Yes ☐ No

If yes please continue, if not please stops

6. How often does your diabetes prevent you from doing your normal daily activities (for example: working or studying)? Circle one number.

1	2	3	4	5	6	7	8	9	10

7. Have you ever attended a diabetes patient education program (a series of classes)?

☐ Yes ☐ No (If yes "Yes", how many years ago? ……………..…)

8. How would you rate your understanding of diabetes and its treatment? Circle one number

1	2	3	4	5	6	7	8	9	10

9. Are you now taking diabetes ☐ ls? Yes ☐ No

10. Please circle the number that indicates how able you are to fit diabetes into your life in a positive manner.

1	2	3	4	5	6	7	8	9	10

Optional participation

11. If you would like to volunteer to help with further research, then please give your contact details:

Name	
E-mail address	
Telephone number	

Section two: attitudes response

For each statement, please put across in the box that most closely matches your level of agreement

Attitude items	Strongly Agree	Agree	Neutral	Disagree	Strongly Disagree
In general, I believe that older people with Type II diabetes do not usually get complications.					
In general, I believe that Type II diabetes is a very serious disease.					
In general I believe that people who have Type II diabetes will probably not get much payoff from tight control of their blood sugars.					
In general I believe that blood sugar testing is not needed for people with Type II diabetes.					
In general I believe that diabetes is hard because you never get a break from it.					
In general I believe that people with diabetes should learn a lot about the disease so that they can be in charge of their own					

diabetes care.					
In general I believe that tight control is too much work.					
In general I believe that it is frustrating for people with diabetes to take care of their disease.					
In general I believe that people with diabetes have a right to decide how hard they will work to control their blood sugar.					

Continue………………

Attitude items	Strongly Agree	Agree	Neutral	Disagree	Strongly Disagree
In general I believe that people who take diabetes pills should be as concerned about their blood sugar as people who take insulin.					
In general I believe that people with diabetes have the right not to take good care of their diabetes					
In general I believe that support from family and friends are important in dealing with diabetes.					
In general I believe that having diabetes changes a person's outlook on life.					
In general I believe that low blood sugar reactions make tight control too risky for most people.					
In general I believe that people with diabetes should have the final say in setting their blood glucose goals					
In general I believe that the emotional effects of diabetes are pretty small.					
In general I believe that almost everyone with diabetes should do					

whatever it takes to keep their blood sugar close to normal.					
In general I believe that people whose diabetes is treated by just a diet do not have to worry about getting many long-term complications					
In general I believe that keeping the blood sugar close to normal can help to prevent the complications of diabetes.					
In general I believe that the important decisions regarding daily diabetes care should be made by the person with diabetes.					

Continue…………………

Attitude Items	Strongly Agree	Agree	Neutral	Disagree	Strongly Disagree
In general I believe that diabetes affects almost every part of a diabetic person's life.					
In general I believe that there is not much use in trying to have good blood sugar control because the complications of diabetes will happen anyway.					
In general I believe that people who do not need to take insulin to treat their diabetes have a pretty mild disease.					
In general I believe that health care professionals should help patients make informed choices about their care plans.					

Any comments please: (Space provided)

Thank you very much for your cooperation

Appendix 18: The Arabic Version of type II diabetes knowledge questionnaire

إستبيان لمعرفة مدى وعيك بمرض السكري النوع الثاني

الجزء الاول: معلومات شخصية عنك

ما تاريخ الولادة:

............../................../.............

هل أنتَ/أنتِ

ا) ذكر ( ) ب)أنثى ( )

منذ متى أصبت بمرض السكر؟

..................سنوات او......................شهور او ....ايام

ما نوع السكري الذي أنت مصاب به

ا)النوع الاول ب)النوع الثاني ج)غير متاكد

كيف يمكنك وصف كمية المعلومات الشفوية التي تلقيتها حول مرض السكري لأول مرة تم تشخيص لديكَ/لديكِ (ضع علامة × على واحد من الصناديق الآتية):

- ☐ أنا لم اتلق اي معلومات شفوية
- ☐ أنا تلقيت القليل جداً من المعلومات الشفوية
- ☐ أنا تلقيت الكم الجيد من المعلومات الشفوية
- ☐ أنا تلقيت الكم الوفير من المعلومات الشفوية
- ☐ أنا لا اريد أن اتلقى أي معلومات شفوية
- ☐ أنا لا أعلم المسؤل علي و الذي قد تلقى معلومات شفوية عني
- ☐ أنا لا استطيع أن أتذكر أو لا أتذكر

كيف يمكنك وصف كمية المعلومات الكتابية التي تلقيتها حول مرض السكري لأول مرة تم تشخيصه لديكَ/لديكِ (ضع علامة × على صند وق واحد فقط)

- ☐ أنا لم اتلق أي معلومات كتابية
- ☐ أنا تلقيت القليل جداً من المعلومات الكتابية
- ☐ أنا تلقيت الكم الجيد من المعلومات الكتابية
- ☐ أنا تلقيتالمعلومات الكتابية بشكل وأخر وزيادة
- ☐ أنا لا اريد أن اتلقى أي معلومات كتابية
- ☐ أنا لا أعلم المسؤل علي و الذي قد تلقى معلومات شفوية عني
- ☐ أنا لا استطيع ان أتذكر او لا أتذكر

هل تتناول أدوية السكر؟

ا)نعم او ب)لا

لو نعم

ا)تأخذ الحبوب المخفضة لسكر

ب)حمية غذائية وممارسة الرياضة

لو انت تاخذ الحبوب المخفضة للسكر،كم حبة مختلفة تتناولها؟

☐ حبة واحدة ☐ حبتان ☐ 3 حبات

ادا كنت تاخد حبوباً أخرى، لو سمحت وضح لي ....

هل سبق لك ان قابلت شخصاً يعطي دورات تعليمية عن مرض السكري

ا)نعم ب)لا

هل سبق لك ان قابلت اخصائي تغدية

ا)نعم ب)لا

مشاركة اختيارية:

لو أردت المشاركة في الدراسة والاستمرار الرجاء قم بتعبئة الصندوق الذي امامك بالمعلومات الشخصية للاتصال بك:

الاسم	
البريد الالكتروني	
رقم الهاتف	

الجزء الثاني: اختبار الوعي بمرض السكري

هذا الجزء يقيم مدى وعيك وتجربتك الشخصية لمرض السكري (اختر الاجابة الصحيحة بوضع دائرة حول كل إجابة سؤال)

1)مرض السكري هو حالة مرضية التي:

(الرجاء ضع دائرة حول إجابة واحدة فقط)

ا) يمكن علاجها بتبني نمط أو اسلوب حياة صحي

ب) يمكن علاجها بالحبوب أو الأنسولين

ج) حالياً لايمكن علاجها

د) باستمرار تهدد حياة الشخص المصاب عند تشخيصيه لأول مرة

ه) غير متاكد

2)أي من هذه التعبيرات حول مرض السكري والحمية الغذائية يكون صحيحاً

(الرجاء ضع دائرة حول اجابة واحدة فقط)

ا)الاشخاص المصابين يجب أن يتناولوا الأطعمة الخالية من السكر

ب) لابأس بأن تأكل ثلاث وجبات مقلية ثلاث مرات بالأسبوع

ج) اللحم الأحمر هو طعام ملئ بالكربوهيدرات

د) الاكل الذي ينصح بأكله لأي مريض سكري يجب أن يكون قليل الدهون وغنياً بالألياف وبه القليل من السكريات

ه) غير متأكد

3) لماذا الأشخاص المصابين بمرض السكري ينصحون بأن يقيسوا سكر الدم بجهازقياسالسكر بالدم

(الرجاء ضع دائرة حول إجابة واحدة فقط)

ا)لتنبههم الى التغيرات التي تحدث في مستوى سكر الجلوكوز بالدم

ب) لتساعدهم على صنع قرارات صائبة عند ممارسة الرياضة وعلاج هبوط السكر بالدم أو حتى المرض باالأنفلونزا أو نزلة برد

ج) تجعل مريض السكري أكثر ثقة للعناية بمرض السكري لديه

د) كل الاجابات المذكورة اعلاه

4)الطريقة الصحيحة لاستعمال جهاز قياس السكري بالدم هي:

ا)استخدام قطرة صغيرة من الدم لتدلك على معرفة كمية سكر الجلوكوز بالدم عند تلك اللحظة

ب)استعمال قطرات كبيرة من الدم لتدلك على معرفة كمية سكر الجلوكوز بالدم عند تلك اللحظة

ج) استعمال قطرة كبيرة من الدم لتدلك على معرفة كمية سكر الجلوكوز بالدم عند تلك اللحظة

د) استعمال ثلاث قطرات من الدم لتدلك على معرفة كمية سكر الجلوكوز بالدم عند تلك اللحظة

5)المعدل الطبيعي لمستوى سكر الجلوكوز بالدم قبل الاكل لدى المصابين بالنوع الثاني من السكري هو:

ا)70-130 ميليجرام/ديسم لتر

ب) 100-150 ميليجرام/ديسم لتر

ج) 40-80 ميليجرام/ديسم لتر

د) 185-200 ميليجرام/ديسم لتر

6)المعدل الطبيعي لمستوى سكر الجلوكوز بالدم بعد ساعتين من الاكل هو:

ا)>200 ميليجرام/ديسم لتر

ب) <180 ميليجرام/ديسم لتر

ج) >70 ميليجرام/ديسم لتر

د) >400 ميليجرام/ديسم لتر

7)ماالذي يجب أن يفعله المريض بقراءة جهاز السكري بالدم

ا)يدون جميع القراءات في السجل اليومي بالسكري ويضع علامة على النتائج الاستثنائية

ب) يدون اليوم والتاريخ للقراءات الاستثنائية فقط

8)ماالذي يفعله الشخص المصاب بالسكري عندما يصاب بالمرض (على سبيل المثال:- انفلونزا، اضرابات في المعدة، التهابات)

(الرجاء اختر اكثر من إجابة صحيحة بوضع دائرة حولها او اختر غير متاكد)

ا)التحقق من نسبة سكر الجلوكوز بالدم (كل ساعتين إلى أربع ساعات)

ب) التوقف عن تناول حبوب السكر او الانسولين

ج) الاكثار من شرب السوائل التي لا تحتوي على سكريات لو مستوى سكر الجلوكوز بالدم اكثر من 15 ملي مول/لتر

د) ابحث عن عناية طبية لو شعرت بانك مريض جداً وغير قادر على قباس السكر بالدم

ه) حاول أن تمارس الكثير من الرياضة قدر المستطاع لتقلل من نسبة السكر بالدم

و) غير متأكد

9) ما مشاكل القدمين التي أغلب مرضى السكري خطر لها

(الرجاء اختر أكثر من إجابة صحيحة بوضع دائرة حولها أو اختر غير متأكد)

ا)ضعف الدورة الدموية

ب) فقدان الإحساس بالقدمين

ج) مسمار القدم

د) الالتهابات

ه) غير متأكد

10) كم عدد المرات التي يجب مرضى السكري ممارسة الرياضة

(الرجاء ضع دائرة حول اجابة واحدة فقط)

ا)أغلب أيام الاسبوع على الأقل 30 دقيقة

ب) مرة واحدة في الاسبوع لمدة ساعة كاملة

ج) على الأقل كل خمسة عشر يوما لمدة ساعتين

د) غير متاكد

11) لماذا ممارسة الرياضة بانتظام شيء مفيد لصحتك

(الرجاء اختر أكثر من إجابة صحيحة بوضع دائرة حولها او اختر غير متاكد)

ا)لأنها يمكن أن تساعد في السيطرة على مستوى سكر الجلوكوز بالدم

ب) لأنها يمكن أن تخفض ضغط الدم

ج) لأنها يمكن أن تساعد على تنظيم مزاج الشخص

د) لأنها يمكن أن تساعد في التقليل من الخطر الاصابة بمرض سرطان الجلد

ه) لأنها يمكن أن تخفض من مستوى الكوليسترول

و) غير متاكد

12) لو أن شخصاً أُصيب بهبوط السكر بالدم ماالذي يجب عليه فعله

(الرجاء ضع دائرة حول اجابة صحيحة واحدة فقط)

ا)على الفور ان يتناول حبوب السكر أو الانسولين

ب) أرتاح حتى أشعر بالتحسن

ج) على الفورأشرب عصير سكري أو طعام سكري (على سبيل المثال المشروبات الغازية أو الحلوى)

د) اشرب عصيراً للحمية الغذائية

ه) غير متأكد

13) العناية الجيدة بمرض السكري تقلل ىمن التعرض للمخاطر التالية

(الرجاء اختر اكثر من اجابة صحيحة بوضع دائرة حولها او اختر غير متاكد)

ا)الفشل الكلوي

ب) العمى

ج) سرطان الجلد

د) أمراض القلب

ه) تقرحات القدم

و) غير متأكد

14) مريض السكري بحاجة الى فحص طبي للعيون والاعصاب ووظائف الكلى على الاقل كل:

(الرجاء ضع دائرة حول اجابة صحيحة واحدة فقط)

ا)كل شهر

ب) كل ستة اشهر

ج) مرة واحدة في السنة

د) غير متأكد

15) اياً من التعبيرات التالية حول الدواء لعلاج السكري صحيحة

(الرجاء ضع دائرة حول اجابة صحيحة واحدة فقط)

ا)اذا كان مستوى السكر بالدم طبيعي لمدة شهرين، يمكن ايقاف تناول دواء السكر

ب) الحبوب أو الأقراص التي تستعمل لعلاج السكر تعمل على رفع مستوى سكر الجلوكوز بالدم

ج) الفحص الطبي المنتظم ضروري لتقييم ماإذا كان المريض بحاجة الى ضبط أدوية السكر

د) الأشخاص الذين يتناولون أدوية السكر لا يحتاجون أن يقلقوا بشأن تناول الأكل الصحي

ه) غير متاكد

أي تعليقات

شكراً لتعاونكم ومساعدتك

Appendix 19: The Arabic Translation version of type II diabetes self-management for patients

استبيان حول الادارة الذاتية لمرض السكري النوع الثاني

الأسئلة التي في الأسفل تسأل عن الرعاية الذاتية لمرض السكري التي قمت أنتَ/أنتِ بها في سبعة أيام مضت. لو كنت مريضاً خلال السبعة الايام الماضية الرجاء أن تفكر في السبعة الأيام الماضية عندما لم تكن مريضاً

(الرجاء ضع علامة (×)على رقم واحد من الأرقام الموجودة أمامك)

1)الحمية الغذائية:-

الحمية الغذائية	عدد الأيام						
	1	2	3	4	5	6	7
في المتوسط، خلال الشهر الماضي كم يوماً في الاسبوع كنت تتبع خطة تناول الطعام الخاصة بك							
كم مرة في السبعة الايام الماضية اكلت خمسة حصص أو أكثر من الفواكه والخضروات							
كم مرة في السبعة الايام الماضية اكلت أطعمة مليئة بالدهون او غنية بالدهون على سبيل المثال: اللحوم الحمراء أو منتجات الألبان كاملة الدسم							
كم مرة في السبعة الايام الماضية اكلت الأطعمة التي تحتوي على الكربوهيدرات على فترات متباعدة خلال اليوم							
كم مرة في السبعة الايام الماضية اتبعت نظاماً غذائياً صحياً							

2) ممارسة التمارين الرياضية:-

ممارسة التمارين الرياضية	عدد الأيام						
	1	2	3	4	5	6	7
كم مرة في السبعة الأيام الماضية مارست الرياضة على الاقل 30 دقيقة							
كم مرة في السبعة الأيام الماضية شاركت في دورات خاصة بالرياضة على سبيل المثال: رياضة السباحة، المشي، رياضة الدراجات غير الرياضة التي تمارسها حول المنزل أو تعتبر جزءاً من شغلك							

3) قياس سكر الدم:-

قياس سكر الدم	عدد الأيام						
	1	2	3	4	5	6	7
كم مرة في السبعة الأيام الماضية قمت بقياس سكر الدم							
كم مرة في السبعة الأيام الماضية قمت بقياس سكر الدم وإتبعت عدد المرات المنصوح بها من قبل الدكتور المختص							

4) العناية بالقدمين:-

العناية بالقدمين	عدد الأيام						
	1	2	3	4	5	6	7
كم مرة في السبعة الأيام الماضية قمت بفحص قدميك							
كم مرة قي السبعة الأيام الماضية قمت بالفحص داخل حذائك							

5) التدخين:-

ا)هل قمت بتدخين سيجارة واحدة في السبعة الأيام الماضية

☐ نعم ☐ لا

عدد السيجارات:- ....

ب) عندما قمت بزيارة الطبيب، هل سألك عن حالة التدخين

☐ نعم أو ☐ لا

ج) فيما لو كنت مدخناً، عند زيارتك السابقة للطبيب، هل استشارك الطبيب بأن توقف التدخين اوأ حالك لأي جهة أو جمعية تقوم ببرنامج إيقاف التدخين

☐ نعم ☐ لا ☐ لا أدخن

د) متى أخر مرة أخذت فيها سيجارة

☐ أكثر من سنتين ماضيتين أو إطلاقا لم أتعاطى التدخين

☐ من سنة إلى سنتين ماضيتين

☐ من أربعة إلى إثنتى عشراً شهراً مضى

☐ من شهر إلى ثلاثة أشهر ماضية

☐ اليوم

6) نصائح الرعاية الذاتية:-

ا)أي من فرق الرعاية الصحية (الطبيب، الممرض/ة، اخصائي التغذية او الصيدلي) نصحك بان تقوم بفعله:
الرجاء التاكد من انك تقوم بهذه الافعال:

- [ ] إتباع نظام غذائي يحتوي على القليل من الدسم
- [ ] إتباع حمية غذائية تحتوي على كربوهيدرات معقدة
- [ ] الخفض من عدد السعرات الحرارية التي تأكلها حتى تخفض من وزنك
- [ ] تناول الطعام الغني والملئ بالالياف
- [ ] تناول الكثير من الفواكه والخضروات (على الأقل خمسة حصص في كل يوم)
- [ ] تناول القليل جداً من الحلويات (على سبيل المثال: الحلويات، بترا صودا محلاة، قطع من الحلوى)
- [ ] أشياء أخرى (حدد): ....
- [ ] أنا لم اتلق أي نصيحة حول الحمية الغذائية من فرق الرعاية الصحية

ب) أي من فرق الرعاية الصحية (الطبيب، الممرض/ة، اخصائي التغذية او الصيدلي) نصحك بأن تقوم بفعله:
الرجاء التأكد من أنك تقوم بهذه الأفعال:

- [ ] القيام بممارسة الرياضة الخفيفة (مثل:- المشي) على أساس يومي
- [ ] القيام بممارسة الرياضة بإستمرار على الأقل 20 دقيقة ثلاث مرات بالإسبوع
- [ ] القيام بممارسة الرياضة يومياً على إعتبارها روتين يومي (مثلاً: الصعود بالدرج بدل السلم، إيقاف سيارتك بمكان بعيد والذهاب على قدميك ماشياً إلخ .....)
- [ ] المشاركة في كمية محددة ونوع ومدة معينة من ممارسة الرياضة
- [ ] أشياء أُخرى (حدد): ....
- [ ] أنا لم أتلق أي نصيحة حول ممارسة الرياضة من فرق الرعاية الصحية

ج)) أي من فرق الرعاية الصحية (الطبيب، الممرض/ة، اخصائي التغذية او الصيدلي) نصحك بأن تقوم بفعله:
الرجاء التأكد من أنك تقوم بهذه الأفعال:

- [ ] إختبار نسبة السكر بالدم بإستعمال قطرة من الدم من إصبعك
- [ ] إختبار نسبة السكر بالدم بإستعمال جهاز لقراءة نتائج السكر بالدم
- [ ] إختبار البول إذا كان به سكر
- [ ] أشياء أُخرى (حدد): ....
- [ ] أنا لم اتلق أي نصيحة حول إختبار نسبة السكر بالدم او البول من فرق الرعاية الصحية

د) أي من هذه الأدوية لعلاج مرض السكر طبيبك وصفها لك؟

(الرجاء التأكد من أنك تقوم بهذه الأفعال)

- [ ] إستعمال إبرة الأنسولين مرة أو مرتين باليوم
- [ ] إستعمال إبرة الأنسولين ثلاثة مرات أو اكثر باليوم
- [ ] تناول أقراص لعلاج مرض السكر للتحكم في نسية السكر بالدم
- [ ] أشياء أُخرى (حدد): ....
- [ ] أنا لم يوصف لي الأنسولين ولا الحبوب المخفضة للسكر

شكراً جزيلاً على تعاونكم معنا

Appendix 20: The Translated Arabic version of Type II diabetes Attitudes for patients

إستبيان لمعرفة آراء ووجهات نظر مريض السكري النوع الثاني تجاه الرعاية الصحية لمرض السكر في طرابلس

الجزء الاول: معلومات شخصية

1)ماهو مستواك التعليمي؟

ا)مستوى ابتدائي

ب) مستوى متوسط (تعليم اعدادي او معهد متوسط او ثانوي)

ج) مستوى عالي (تعليم جامعي او معهد عالي)

2) هل انت

ا)ذكر( ) ب) أُنثى ( )

3) كم عمرك؟

---

4) كم مضى على اصابتك بمرض السكري؟

---

5)هل انت مصاب بالنوع الثاني من السكري؟

ا) نعم ب) لا

لو أجبت بنعم الرجاء استمر، اما لو اجبت بلا الرجاء التوقف

6)مااللأنشطة اليومية التي يمنعك مرض السكر من أدائها (على سبيل المثال:- العمل او الدراسة) الرجاء ضع دائرة على رقم واحد من اللأرقام الموجودة امامك

1 2 3 4 5 6 7

يمنعني اكثر من القيام بالنشاطات اليومية

7) هل حضرت من قبل برنامجاً تعليمياً لمرض السكري (سلسلة من الحصص)

ا)نعم ب) لا (لو نعم، كم مرة في السنوات الماضية

....)

8) كيف تقييم فهمك لمرض السكري وعلاجه؟ (ضع دائرة على رقمٍ واحد من الارقام الموجودة امامك)

1 2 3 4 5 6 7

أكثر فهماً

9) هل تتناول الحبوب المخفضة لنسبة الجلوكوز بالدم لعلاج السكري؟

ا)نعم ب) لا

10) الرجاء ضع دائرة حول الرقم الذي يدل على مدى مقدرتك لتكيفك مع مرض السكر في حياتك اليومية بشكل ايجابي

1 2 3 4 5 6 7

أكثر مقدرة على التكيف

مشاركة إختيارية:

لو أردت المشاركة في الدراسة والاستمرار الرجاء قم بتعبئة الصندوق الذي امامك

بالمعلومات الشخصية للاتصال بك:

الاسم	
البريد الالكتروني	
رقم الهاتف	

الجزء الثاني: الاستجابة السلوكية

بند السلوك	موافق بشدة	موافق	محايد	غير موافق	غير موافق بشدة
بشكل عام، أنا أعتقد أن كبار السن المصابين بالنوع الثاني من مرض السكري لا يتعرضون لأي مضاعفات					
بشكل عام، أنا أعتقد أن النوع الثاني من السكر هو مرض خطير جداً					

يتبع....................

بند السلوك	موافق بشدة	موافق	محايد	غير موافق	غير موافق بشدة
بشكل عام، أنا أعتقد أن الاشخاص الذين لديهم مرض السكري النوع الثاني ربما لا يحصلون على الكثير من مردود الرقابة المشددة على نسبة السكر بالدم					
بشكل عام، أنا أعتقد أنَّ الحاجة لفحص السكر بالدم ليست ضرورية لمرضى السكري النوع الثاني					
بشكل عام، انا اعتقد بان مرض السكري مرض صعب لاني لاأستطيع أن أخذ راحة منه					
بشكل عام، أنا أعتقد بأنَّ الأشخاص المصابين بمرض السكر يجب ان يتعلموا الكثير حول المرض ليساعدهم على أن يصبحوا مسؤليين على انفسهم للعناية بمرض السكري					

بشكل عام، اعتقد أنَّ الرقابة المشددة على العناية بمرض السكري هو عمل اكثر من اللازم					
بشكل عام، أنا أعتقد بأنه أمر محبط لمرضى السكرحين يقومون بالعناية بمرضهم					
بشكل عام، أنا أعتقد أن مريض السكري له الحق بأنْ يقرر مدى صعوبة العمل على السيطرة للتحكم في نسبة السكر بالدم					
بشكل عام، أنا اعتقد أن الاشخاص الذين يتناولون الأقراص المخفضة للجلوكوز بالدم ينبغي أن يقلقوا بشان السكر بالدم مثل الاشخاص الذين يعالجون بواسطة الأنسولين					
بشكل عام، انا اعتقد بأنَّ الأشخاص المصابين بمرض السكري لديهم الحق في عدم الرعاية الصحية الجيدة بمرض السكري					

يتبع............

بند السلوك	موافق بشدة	موافق	محايد	غير موافق	غير موافق بشدة
بشكل عام، أنا اعتقد بأن الدعم من الاسرة والاصدقاء مهم في التعامل مع مرض السكري					
بشكل عام، انا اعتقد بأن الشخص المصاب بالسكري يغير من فلسفته للحياة					
بشكل عام، انا اعتقد بأن الهبوط في السكر يجعل مريض السكري في خطر لأنه من الصعب السيطرة عليه					
بشكل عام، أنا اعتقد بأن الاشخاص المصابين بالسكر يجب أن يكون لديهم القول النهائي في تحديد أهدافهم					
بشكل عام، أنا اعتقد بأن الأثار العاطفية لمرض السكر هي صغيرة جداً					
بشكل عام، أنا أعتقد أن أي شخص مصاب بمرض السكري يجب ان يفعل أي شئ ليحافظ على نسبة السكر بالدم قريبة للمعدل الطبيعي					
بشكل عام، انا اعتقد أن الحفاظ على نسبة السكر بالدم قريبة إلى وضعها الطبيعي يمكن أن يساعد على منع مضاعفات مرض السكر					
بشكل عام، انا اعتقد أن القرارات الهامة بشان رعاية مرض السكر اليومية ينبغي ان تصدر من الشخص المصاب بمرض السكر					
بشكل عام، أنا اعتقد أن مرض السكري يؤثر على كل جزء تقريباً من حياة الشخص المصاب بالسكري					
بشكل عام، انا اعتقد أنَّهُ ليس هناك أي فائدة كبيرة من المحافظة على السكر بالدم للمعدل الطبيعي لأن مضاعفات المرض تحدث على أي حال					

يتبع..

بند السلوك	موافق بشدة	موافق	محايد	غير موافق	غير موافق بشدة
بشكل عام، أنا أعتقد أن الاشخاص الذين لا يحتاجون الى اخذ الانسولين لعلاج مرض السكري يعتبر مرض السكري لديهم خفيفاً					
بشكل عام، انا اعتقد ان المتخصصين في الرعاية الصحية من شأنه أن يساعد المرضى على اتخاذ قرارات مستنيرة بشأن مخطط الرعاية الصحية بمرض السكري					
بشكل عام، أنا أعتقد أن المتخصصين في الرعاية الصحية يجب ان يتعلموا كيفية وضع أهداف مع المرضى، وليس أن تقول لهم ماالذي يجب فعله فقط					
بشكل عام، أنا أعتقد أن الشخص المصاب بمرض السكري هو الشخص الأكثر أهمية أو هو العضو الأكثر أهمية في فريق الرعاية الصحية بمرض السكري					

الرجاء أي ملاحظات

شكراً جزيلاً على تعاونكم معنا

Appendix 21: Patient Information Sheet

Patient information sheet

Medicine management for type II diabetic patients in Tripoli

You are being invited to take part in a research study. Before you decide it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with friends, relatives and your physician if you wish. Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part.

What is the purpose of the study?

The general aim of this study is to improving the control of your diabetes. You will complete some questionnaires and we will interview you. We will help you to look after yourself and control your diabetes. We will collect records of your blood sugar levels for 6 months.

Why have I been chosen?

Your community pharmacist has approached you because you are a regular customer, you have diabetes and you are at least 40 years old. We will recruit about 300 patients.

Do I have to take part?

It is up to you to decide whether or not to take part. If you do decide to take part you will be given this information sheet to keep and be asked to sign a consent form. If you decide to take part you are still free to withdraw at any time and without giving a reason. This will not affect the standard of care you receive.

What will happen to me if I take part?

First you would fill in three questionnaires about: awareness of diabetes, attitudes and self-management. The pharmacist will give you these questionnaires and a glucose meter. We will ask you to keep records of your glucose levels. You will need to visit the pharmacy once a month for 6 months.

We will also ask you to get a HbA1c test (long term glucose measure) at the start and the end of the study.

This study is a controlled trial. Half the participants will receive normal care and have some extra glucose monitoring (control group). Half the participants will receive extra help from us to control their diabetes (intervention group).

What do I have to do?

If you complete the questionnaires, then we will give you a score. If you are in the intervention group, we will discuss the best answers to the questions and agree a list of things for you to do. These actions should help you to control your glucose levels. We will ask all participants (control and intervention) to monitor their glucose regularly.

What are the possible disadvantages and risks of taking part?

In this study we want to help you to control your own diabetes. The things we suggest you do will be based on the based current evidence. We will not change the medicines your doctor has prescribed. We will try to improve your knowledge and skills. There are no medical risks to taking part. Thinking more about your diabetes may make you worried or anxious. So please tell us if this happens. If you feel unwell at any point please discuss it with your doctor or pharmacists as normal.

What are the possible benefits of taking part?

You will learn more about diabetes and how to manage the condition. Many people find that setting goals and learning to help themselves is rewarding. We hope that the control of your diabetes will get better. We cannot promise this will happen. The results of the study will help us to design better services for other people.

Will my taking part in this study be kept confidential?

All information collected about you during this research study will be kept private. Any information about you will have your name and address removed so that you cannot be recognised from it.

The results of the study will be analysed by the University of Bradford and a report will be written. You will not be able to be identified in the report.

What will happen to the results of the research study?

We hope the study results will be published in medical journals. We will send you and your pharmacist a short summary.

Who has reviewed the study?

The study has been given ethical approval by the University of Bradford's ethics committee.

Contacts for Further Information

Should you require any further information then please contact PhD student: Nesrin Mohamed Elhatab, school of Pharmacy, University of Bradford, BD7 1DP, Tel no: 0044-7735095109, email address: nmaelhat@student.bradford.ac.uk& Dr Jonthan Silcock Senior Lecturer in Pharmacy Practice, Bradford School of Pharmacy, University of Bradford, Bradford, West Yorkshire, BD7 1DP, Telephone: 44(0)1274 236624, email address: j.silcock@bradford.ac.uk, if you speak English.

Appendix 22: Consent form for patients

CONSENT FORM

Title of Project: Medicine management for type II diabetic patients in Tripoli

Name of Researcher: Nesrin Mohgamed Elhatab& Dr Jonathan Silcock& Dr Anne Graham

Please initial all boxes

1. I confirm that I have read and understand the information sheet for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.

2. I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason, without my medical care or legal rights being affected.

3. I understand that relevant sections of my medical notes and data collected during the study may be looked at by individuals from University of Bradford, where it is relevant to my taking part in this research. I give permission for these individuals to have access to my records.

4. I agree to my GP being informed of my participation in the study.

5. I agree to take part in the above study.

Name of Participant	Date	Signature
Name of Person Taking consent	Date	Signature

Appendix 23: Randomisation of community pharmacies

Table 10.1: Cluster randomisation for 40 community pharmacy in Tripoli/ Libya

Name of street or area	Number of Geographic areas that participated in the study	Cluster sampling	Type of area
Abou Meshmasha	1		Residential
Abou Meshmasha	1		Commercial
Abu seta	2		Residential
Abu seta	2		Residential
Abu seta	2		Commercial
Abusalim	3		Commercial
Abusalim	3		Commercial
Ain Zara	4	1	Commercial
Alhadba Alkhadra	5	1	Commercial
Alhadba Alkhadra	5	1	Commercial
Almaanshea	6		Residential

Almaanshea	6		Commercial
Almadena	7		Commercial
Almadeena	7		Commercial
Alnaser street	8	1	Residential
Al-Noflyeen Street	9	1	Commercial
Al-Noflyeen Street	9	1	Residential
Al-Noflyeen Street	9	1	Commercial
Alrashed street	10	1	Commercial
Alsaha Alkhadra	11		Residential
Alsharaa Al-Gharbi	12	1	Commercial
Alsharqia	13		Residential
Alsharqia	13		Residential
Alsyahia	14		Commercial
Assreem Street	15		Residential
Bab Alazezeya	16		Commercial
Bab Alazezeya	16		Commercial
Bab Alazezeya	16		Commercial

Bab Alazezeya	16		Commercial
Bab Alazezeya	16		Commercial
Bab Alazezeya	16		Commercial
Bab Ben Ashur street	17		Commercial
Bab Ben Ashur street	17		Commercial
Bab Ben Ashur street	17		Residential
Bab Ben Ashur street	17		Residential
Bab Ben Ashur street	17		Residential
Bab Ben Ashur street	17		Commercial
Bab Ben Ashur street	17		Commercial
Bab Ben Ashur street	17		Residential
Bab Ben Ashur street	17		Commercial
Bab Ben Ashur street	17		Commercial
Bab Ben Ashur street	17		Commercial
Bab Ben Ashur street	17		Commercial
Bab Ben Ashur street	17		Commercial
Bab ben Gashir	18		Commercial

Bab Ben Ghashir	18		Commercial
Bab Ben Ghashir	18		Residential
Bab ben Gashir	18		Commercial
Bab Ben Ghashir	18		Residential
Bab ben Gashir	18		Residential
Bab ben Gashir	18		Commercial
Bohrida Street	19		Commercial
Duriby	20	1	Commercial
Duriby	20	1	Residential
Duriby	20	1	Commercial
Fashlum	21		Commercial
Fashlum	21		Commercial
Fashlum	21		Commercial
Gaser Ben Ghashir	22		Residential
Gaser Ben Ghashir	22		Commercial
Gorji Street	23		Residential
Gorji Street	23		Residential

Gorji Street	23		Residential
Got Alshaal	24	1	Residential
Got Alshaal	24	1	Commercial
Got Alshaal	24	1	Residential
Heshan	25		Commercial
Hi alzuhur	26		Residential
Hi Damascus	27	1	Commercial
Hialandules	28		Residential
Janzur	29		Residential
Janzur	29		Commercial
Janzur	29		Residential
Midan Aljazear	30	1	Commercial
Omar Almoukhtar Street	31	1	Commercial
Raashasan	32		Commercial
Salah Alden	33		Commercial
Salah Alden	33		Residential
Salah Alden	33		Residential

Salah Alden	33		Commercial
Salah Alden	33		Commercial
Salah Alden	33		Commercial
Salah Alden	33		Residential
Sharaa Azzawya	34	1	Residential
Sharaa Azzawya	34	1	Commercial
Sharaa Azzawya	34	1	Commercial
Sharaa Azzawya	34	1	Residential
Sharaa Azzawya	34	1	Residential
Sharaa Azzawya	34	1	Commercial
Sharaa Azzawya	34	1	Residential
Sharaa Azzawya	34	1	Residential
Sharaa Azzawya	34	1	Residential
Sharaa Azzawya	34	1	Residential
Shreea Aldel	35		Commercial
Sidi Almasri	36	1	Residential
Sooq Al-Gomaa	37	1	Commercial

Sooq Al-Gomaa	37	1	Residential
Sooq Al-Gomaa	37	1	Commercial
Sooq Al-Gomaa	37	1	Commercial
Sooq Al-Gomaa	37	1	Residential
Sooq Al-Gomaa	37	1	Commercial
Sooq Al-Gomaa	37	1	Residential
Sooq Al-Gomaa	37	1	Residential
Sooq Al-Gomaa	37	1	Commercial
Soug Al Sabt	38	1	Commercial
Souk Elthoulatha	39	1	Commercial
Zawiat Aldehmany	40		Residential
Zawiat Aldehmany	40		Residential

Appendix 24: Geographical location of community pharmacies

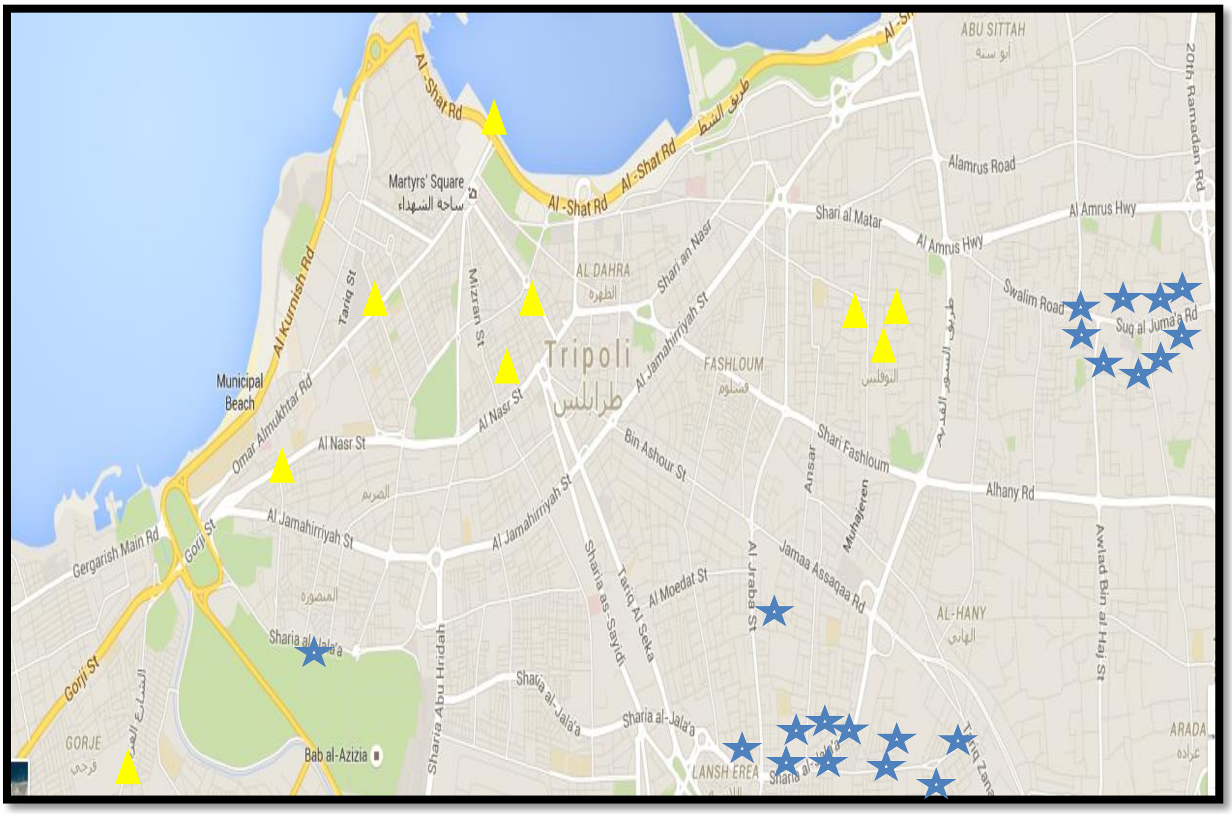

Figure 10.1: Geographical areas for community pharmacies participating in clinical trial (blue stars intervention pharmacies and yellow triangles control pharmacies)

Figure 10.2: Geographical areas for community pharmacies participating in clinical trial

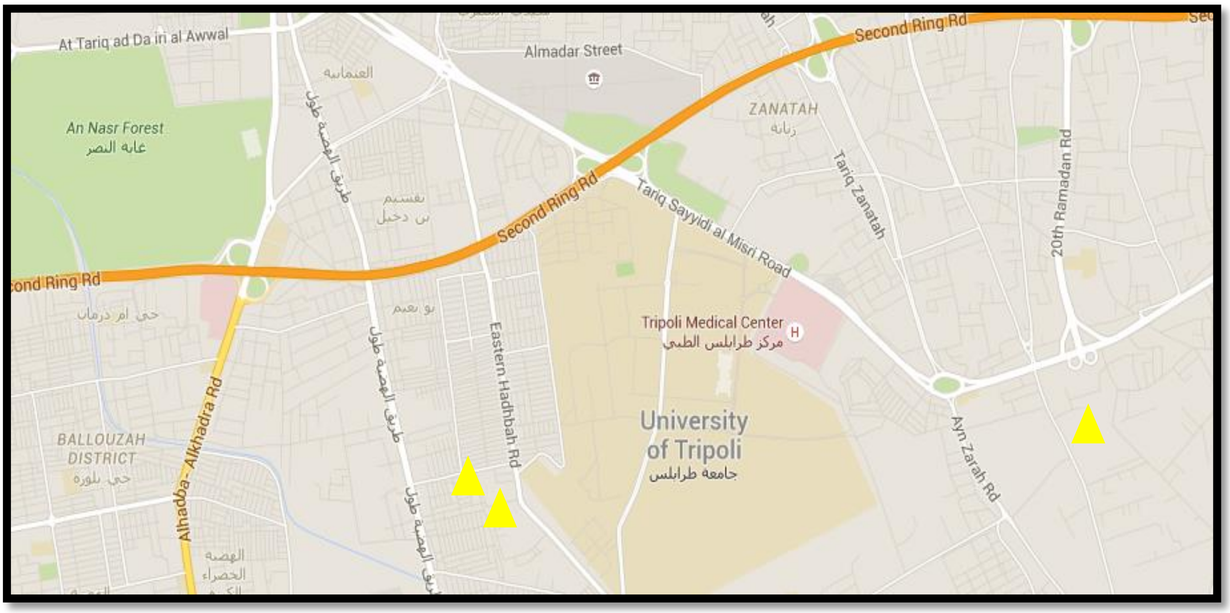

Figure 10.3: Geographical areas for community pharmacies participating in clinical trial

Appendix 25: Arabic leaflet about diet choices for diabetic people

التحدث حول السكري رقم 15
تمت المراجعة في آب/ أغسطس 2010

الخيارات الغذائية لمرضى السكري

food choices for people with diabetes - Arabic

الأكل الصحي، جنبا إلى جنب مع النشاط البدني المنتظم، يمكن أن يساعدك على إدارة مستويات الجلوكوز في الدم، وخفض الدهون (الكولسترول والدهون الثلاثية) في دمك والحفاظ على وزن صحي. إرجع إلى صحيفة معلومات النشاط البدني والسكري من النوع 2 لمعرفة المزيد عن كيف أن تكون نشيطا كل يوم.

ماذا يجب أن آكل؟

للمساعدة في إدارة مرض السكري الخاص بك، فإن وجبات طعامك في حاجة إلى أن تكون:

- ذات حجم مناسب ـ ليست كبيرة جدا
- عادية وموزعة بالتساوي على مدار اليوم
- منخفضة الدهون، وخاصة الدهون المشبعة
- مبنية على الأطعمة الكربوهيدراتية العالية الألياف مثل الخبز ذو الحبوب الكاملة وحبوب الإفطار (السيريال)، الفاصوليا المجففة والعدس والخضار النشوية والفاكهة.

في الصفحات التالية، نقدم معلومات حول مختلف أنواع الأطعمة وتأثيرها على صحتنا:

خطة نموذجية لوجبات طعام ليوم واحد:

الأكل الصحي لمرضى السكري لا يختلف عن ذلك الذي يوصى به للجميع. ليست هناك حاجة لإعداد وجبات منفصلة أو شراء أطعمة خاصة، لذلك إسترخ وتمتع بالأكل الصحي جنبا إلى جنب مع العائلة بأكملها!

Appendix 26: Arabic leaflets for patients with diabetes

النشاط البدني ومرض السكري من النوع 2

physical activity & type 2 diabetes - Arabic

الحصول على ما يكفي من النشاط البدني المنتظم أمر مهم للحفاظ على صحة جيدة وضمان الإدارة الجيدة للسكري. في حين قد تفكر "أن قول الشيء أسهل من عمله"، قد تفاجئ بأن تعلم أن ممارسة التمارين ليست حول "لا ألم - لا ربح". النشاط البدني المنتظم يمكن أن يصبح جزءا ممتعاً من يومك مع الفوائد الطويلة الأمد للسكري وصحتك بشكل عام.

لماذا نقوم به؟

النشاط البدني أمر ضروري للجميع للبقاء في صحة جيدة. لمرضى السكري، أن تكون نشيطاً بدنياً بإنتظام له فوائد أكبر.

لمريض السكري، يساعد النشاط البدني على:

- تحسين إستجابة الجسم للأنسولين الذي يمكن أن يخفض مستويات الجلوكوز في الدم
- خفض ضغط الدم ومستويات الكولسترول، وتقليل مخاطر الإصابة بأمراض القلب
- السيطرة على الوزن
- تقليل مخاطر الاصابة بمضاعفات مرض السكري.

الإيجابيات الأخرى تشمل ما يلي:

- عظام أقوى
- زيادة مستويات الطاقة
- تحسين النوم.
- تحسين المزاج
- تقليل الضغط والتوتر

ما هي الأنشطة الموصى بها؟

الأنشطة الرياضية الهوائية التي تؤدي إلى تحريك عضلاتك الكبيرة مثل المشي أو السباحة أو ركوب الدراجات جميعها يوصى بها. ليس كل واحد يجد أن النشاط ممتع، لذلك إختر الأنشطة التي تستمتع بها وتجعلك تتحرك.

أنشطة تدريب القوة التي تجعلك تستخدم عضلاتك ضد المقاومة، مثل القرفص أو رفع الأثقال، يوصى بها أيضا.

أفكار لمساعدتك على "التحرك":

- المشي هو سهل ولا يكلف شيئا ولا يحتاج إلى أي مهارة خاصة - مجرد زوج جيد من أحذية المشي. قم بزيادة السرعة والمسافة المقطوعة عندما تصبح لائقاً بدنياً.
- كن خلاقا وحاول شيئاً مختلفاً - ربما الرقص، أو التمارين الرياضية المائية، أو المشي في المياه أو تاي تشي. تحقق من المركز المجتمعي المحلي حول البرامج المجانية.

يتبع في الجانب الآخر ...

النشاط البدني يفيد الجميع بطرق كثيرة ولكن لمرضى السكري، فأن يكونوا نشيطين بدنيا بإنتظام، وأن يتناولون الطعام الجيد وأن لا يدخنون مهم جدا لصحتهم في المستقبل.

التحدث حول السكري رقم 33
تمت المراجعة في آب/ أغسطس 2010

أيام المرض ومرض السكري من النوع 2

sick days & type 2 diabetes - Arabic

سوف يسبب المرض اليومي أو الإصابات تقريباً دائما إرتفاعا في مستويات الجلوكوز في الدم إذا كان لديك مرض السكري من النوع 1 أو من النوع 2. لذلك، في أول علامة لأي شكل من أشكال المرض مثل برد أو فيروس، فمن المهم بالنسبة لك إتخاذ الإجراءات اللازمة.

أخبر أي شخص	متى تتصل الطبيب
1. أخبر أي شخص إذا كنت وحدك، أخبر شخص ما بأنك مريض حتى يتمكنوا من مراقبتك.	إذا كنت بحاجة إلى مساعدة و "مقدم الرعاية" الخاص بك غير قادر على مساعدتك، أطلب منهم الاتصال بطبيبك.
2. الإختبار إفحص مستويات الجلوكوز في الدم على الأقل مرة كل 2-4 ساعات (اهداف مثالية عندما تكون بصحة جيدة هي 6-8 مليمول / لتر قبل الوجبات و6-10 مليمول / لتر بعد وجبات الطعام (ساعتين بعد بدء الوجبة)). إرجع إلى صحيفة معلومات مراقبة الجلوكوز لمزيد من التفاصيل..	
3. إستمر في الشرب و (إن أمكن) الأكل إذا كنت تأخذ الأنسولين أو أقراص السكري، فمن المهم تجنب الهايبو غليسيميا - أنظر أدناه ومن المهم أيضا تجنب الجفاف عن طريق شرب السوائل غير المحلاة الإضافية كل ساعة مثل الماء، المشروبات الغازية الدايت، شراب الدايت، شاي خفيف، قهوة، عصير الخضار أو مرق اللحم.	
• إذا كنت تستطيع الأكل بشكل طبيعي إستمر في الأكل كالمعتاد و إشرب نصف كوب – كوب إضافي من السوائل غير المحلاة (على النحو الوارد أعلاه) كل ساعة.	اتصل بطبيبك. سوف تحتاج ربما الإستمرار في أخذ أقراص السكري أو الأنسولين، وسوف تحتاج إلى نصيحة حول ما يجب فعله.
• إذا كنت لا تستطيع الأكل بشكل طبيعي تناول بعض من المشروبات أو الوجبات الخفيفة أو الوجبات الصغيرة الكربوهيدراتية التي يسهل أكلها كل 1-2 ساعة (أنظر الإقتراحات على صفحة 2).	
• إذا كنت لا تستطيع الأكل على الإطلاق، ومستوى الجلوكوز في الدم: is • أكثر من 15 مليمول / لتر: إشرب السوائل غير المحلاة كما هو مذكور أعلاه. • أقل من 15 مليمول / لتر: إشرب السوائل المحلاة على النحو الوارد في الصفحة 2	اتصل بطبيبك إذا كنت لا تستطيع الأكل على الإطلاق. اتصل بطبيبك إذا كان مستوى الجلوكوز في الدم أكثر من 15 مليمول / لتر بشكل مستمر لأكثر من 12 ساعة. اتصل بطبيبك إذا: • إستمر القيء أو الإسهال لأكثر من 12 ساعة. • كنت لا تزال تشعر بتوعك أو نعس.

عندما تكون مريضاً، إفحص مستويات الجلوكوز في الدم أكثر ، إستمر في الشرب، وإذا أمكن، تناول الطعام ـ وإسترح. كن على علم أنه قد يكون هناك أوقات عندما ستحتاج إلى الاتصال بطبيبك أو مثقف السكري.

ما هو مرض السكري؟

من سيساعدني؟

تتم إدارة حالة لمدى الحياة مثل السكري بشكل أفضل مع دعم من فريق السكري، والتي أنت أهم عضو فيه. يشمل الأعضاء الآخرين طبيبك، مثقف السكري، إختصاصي التغذية وإختصاصي الأقدام. حسب إحتياجاتك، قد يشمل أيضا الفريق الإختصاصيين الطبيين، إختصاصي التمارين الفيزيولوجية والمستشارين.

سوف يساعدك فريقك على تعلم كل ما تحتاج لمعرفته حول مرض السكري الخاص بك.

وسوف يكونوا هناك لدعمك، ومع توجيهاتهم سوف تصبح قريبا واثقا من إتخاذ القرارات اليومية لحياة لائقة وصحية.

المبادئ التوجيهية الأساسية للإعتناء بمرض السكري الخاص بك

هناك العديد من الخطوات التي يمكنك إتخاذها لرعاية مرض السكري الخاص بك. وإليك بعض النصائح:

- إرتبط مع فريق السكري في منطقتك. في بعض الحالات، قد يحتاج طبيبك لإحالتك.
- إفحص مستويات الجلوكوز في الدم بإنتظام.
- دائما خذ الأنسولين (بالنسبة لأولئك الذين يحتاجون اليه).
- إذا أعطاك طبيبك أقراص للمساعدة في إدارة مرض السكري، ضغط الدم و/ أو الكولسترول الخاص بك، تأكد من أخذها.
- كن نشطاً بقدر الإمكان.
- إتبع خطة الأكل الصحي.
- حقق وحافظ على وزن وشكل جسم أكثر صحة (إرجع إلى صحائف معلومات وزن أقل ، شكل أكثر صحة).
- حافظ على موقف عقلي إيجابي.
- لا تخاف من طلب المساعدة في أقرب وقت تشعر بأنك في حاجة إليها.

هل ترغب في الإنضمام إلى منظمة السكري الرائدة في استراليا؟

< الخدمات الغذائية < مجلات مجانية < خدمات الطفولة

< الأدب التثقيفي < خصومات على المنتج < مجموعات الدعم

لمزيد من المعلومات اتصل على **1300 136 588** أو قم بزيارة موقع المنظمة في ولايتك / إقليمك:

NSW	www.australiandiabetescouncil.com	**ACT**	www.diabetes-act.com.au
QLD	www.diabetesqueensland.org.au	**NT**	www.healthylivingnt.org.au
TAS	www.diabetestas.com.au	**SA**	www.diabetessa.com.au
WA	www.diabeteswa.com.au	**VIC**	www.diabetesvic.org.au

تصميم ومحتوى وإنتاج صحيفة معلومات مرض السكري هذه أجري من قبل:

< ACT Diabetes ACT < NSW Australian Diabetes Council
< NT Healthy Living NT < QLD Diabetes Australia – Queensland
< SA Diabetes SA < TAS Diabetes Tasmania
< VIC Diabetes Australia – Vic < WA Diabetes WA

المحتوى الطبي والتعليمي الأصلي لصحيفة المعلومات هذه تم مراجعته من قبل لجنة الرعاية الصحية والتعليم للسكري استراليا المحدودة.

وبالنسبة لأي مسائل تتعلق بصحيفة المعلومات هذه يرجى الإتصال بالمنشورات الوطنية على dapubs@tpg.com.au أو الاتصال على 02 9527 1951.

الإختصاصيين الصحيين: للحصول على نسخ جديدة من هذا المورد، اتصل بمنظمة السكري في ولايتك / إقليمك على النحو الوارد.

تمت المراجعة في آب/ أغسطس 2010 سلسلة معلومات السكري من منظمات السكري في الولاية / الإقليم - حقوق الطبع والنشر © 2010

التحدث حول السكري رقم 04
تمت المراجعة في آب/ أغسطس 2010

مراقبة نسبة الجلوكوز في الدم

blood glucose monitoring - Arabic

المراقبة الذاتية للجلوكوز في الدم هي أداة قيّمة لإدارة مرض السكري، والتي تمكّن الناس من فحص مستويات السكر في الدم بقدر ما يحتاجون إليه أو على النحو الموصى به.

لماذا فحص دمي مهم جدا؟

الفحص والتسجيل المنتظم لمستوى الجلوكوز في الدم يمكن أن يعزز إختيارات نمط الحياة الصحي الخاص بك وكذلك إعلامك حول إستجابتك للخيارات والتأثيرات الأخرى.

الأهم من ذلك، إن تغيرات نمط مستوى الجلوكوز في الدم يمكن أن ينبهك وينبه فريق الرعاية الصحية الخاص بك لإحتمال الحاجة إلى إجراء تغيير في الطريقة التي يدار بها مرض السكري الخاص بك.

سوف يساعدك فحص مستويات الجلوكوز في الدم في:

- تطوير الثقة في رعاية مرض السكري الخاص بك.
- فهم أفضل للعلاقة بين مستويات الجلوكوز في الدم، والتمارين التي تقوم بها، الطعام الذي تتناوله وتأثيرات نمط الحياة الأخرى مثل السفر والإجهاد والمرض.
- معرفة كيف أن إختيارات نمط حياتك والدواء، إذا استخدم، يعملوا فرقاً.
- إعرف على الفور ما إذا كانت مستويات الجلوكوز في الدم مرتفعة جدا (فرط سكر الدم-هايبر غليسيميا) أو منخفضة جدا (هايبو غليسيميا) ، مما يساعدك على إتخاذ قرارات مهمة مثل تناول الطعام قبل ممارسة التمارين، وعلاج 'الهايبو' أو طلب المشورة الطبية إذا كنت مريضاً. (إرجع إلى صحيفة المعلومات الفردية *على النشاط البدني والسكري من النوع 2؛ هايبو غليسيميا والسكري؛ أيام المرض والسكري من النوع 1، أيام المرض والسكري من النوع 2).*
- معرفة متى تطلب المشورة من فريق السكري الصحي الخاص بك حول ضبط الأنسولين، الأقراص، تخطيط وجبة الطعام أو الوجبات الخفيفة عندما لا يتم تلبية أهداف الجلوكوز في الدم.

ويمكن لإختصاصي الصحة لمرض السكري مثل مثقف السكري أن يساعدك على إختيار الجهاز الأفضل بالنسبة لك. مثقف السكري أيضا سوف يعطيك كل المعلومات التي تحتاجها حول كيف وأين ومتى تقوم بفحص مستويات الجلوكوز في الدم ويعمل معك في التخطيط لروتين يعمل بالنسبة لك وللحياة التي تقودها.

هايبو غليسيميا والسكري

ماذا ينبغي أن أفعل أيضاً؟

- إرتدي هوية تبين بأن لديك سكري.
- أكتب ملاحظة في كتاب المراقبة لأي 'هايبو' عانيت منها وناقشها مع طبيبك أو مثقف السكري في زيارتك المقبلة.
- تأكد من أن الأسرة والأصدقاء وزملاء العمل وموظفي المدرسة ومقدمي الرعاية يعرفون كيفية معرفة وعلاج الهايبو غليسيميا.
- ابحث عن سبب 'الهايبو' حتى تتمكن من محاولة منع الحالة من الحدوث مرة أخرى.
- اتصل بطبيبك أو مثقف السكري إذا كنت تعاني من 'الهايبو' بشكل متكرر.
- إذا كنت تأخذ دواء يدعى اكاربوز (جلوكوباي®) (Acarbose (Glucobay®)، إحمل معك جلوكوز نقي مثل أقراص الجلوكوز أو هلام الجلوكوز أو لوكوزايد.
- إرجع إلى صحيفة معلومات الكحول والسكري لمزيد من النصائح حول شرب الكحول والهايبو غليسيميا.
- تناول النشويات إذا كنت تشرب الكحول.
- قبل قيادة السيارة، إفحص مستوى الجلوكوز في الدم وتأكد من أنه أعلى من 4 مليمول / لتر.
- هل ترغب في الإنضمام إلى منظمة السكري الرائدة في استراليا؟

هل ترغب في الإنضمام إلى منظمة السكري الرائدة في استراليا؟

- الخدمات الغذائية
- مجلات مجانية
- خدمات الطفولة
- الأدب التثقيفي
- خصومات على المنتج
- مجموعات الدعم

لمزيد من المعلومات اتصل على **1300 136 588** أو قم بزيارة موقع المنظمة في ولايتك / إقليمك:

NSW	www.australiandiabetescouncil.com	**ACT**	www.diabetes-act.com.au
QLD	www.diabetesqueensland.org.au	**NT**	www.healthylivingnt.org.au
TAS	www.diabetestas.com.au	**SA**	www.diabetessa.com.au
WA	www.diabeteswa.com.au	**VIC**	www.diabetesvic.org.au

تصميم ومحتوى وإنتاج صحيفة معلومات مرض السكري هذه أُجري من قبل:

- ACT Diabetes ACT
- NSW Australian Diabetes Council
- NT Healthy Living NT
- QLD Diabetes Australia – Queensland
- SA Diabetes SA
- TAS Diabetes Tasmania
- VIC Diabetes Australia – Vic
- WA Diabetes WA

المحتوى الطبي والتعليمي الأُصلي لصحيفة المعلومات هذه تم مراجعته من قبل لجنة الرعاية الصحية والتعليم السكري استراليا المحدودة.

وبالنسبة لأي مسائل تتعلق بصحيفة المعلومات هذه يرجى الإتصال بالمنشورات الوطنية على dapubs@tpg.com.au أو الاتصال على 02 9527 1951.

الإختصاصيين الصحيين: للحصول على نسخ عديدة من هذا المورد، اتصل بمنظمة السكري في ولايتك / إقليمك على النحو الوارد.

تمت المراجعة في آب/ أغسطس 2010 سلسلة معلومات السكري من منظمات السكري في الولاية / الإقليم -

Appendix 27: Ethical approval

APPLICANT'S ETHICS CHECKLIST

This checklist is designed to help you to decide whether or not ethics approval is required and, if required, to decide on the appropriate ethics review procedure –
please read Annex 1 on page 5 before you complete this form

Please Note:

a) This Checklist should be completed for all research projects involving human participation.

b) All questions on this checklist should be completed.

c) Contact details (email address) should be given for PI or PS and student (if applicable).

d) In the case of Student projects, Supervisors should read and sign this checklist (in the correct box – EITHER/OR – not both boxes) BEFORE it is submitted to the Ethics Administrator for sign off by the Chair of the Research Ethics Panel.

e) Guidance on the 2 different ethics review procedures that together make up the University's Ethics Review System (i.e. 'University' and 'NHS') is available on the University Ethics website.

f) If your project will involve human tissue/biological fluids you should contact the UoB Designated Individual for the HTA licence, Dr Sue Boyce for advice (s.g.boyce@bradford.ac.uk or on 01274 235879)

g) **If this Checklist is NOT correctly completed, it will be returned to you unauthorised.**

Project Title: Medicine management of type II diabetes

Name of Principal Investigator / Principal Supervisor: - Dr Jon Silcock

Contact Details – email address: j.silcock@bradford.ac.uk

Department/School:- PhD Pharmacy& Pharmaceutical Innovation

Name of Student (if applicable)**:- Nesrin Mohamed Elhatab**

Contact Details – email address:- nmaelhat@student.bradford.ac.uk

Has student attended appropriate ethics training: Yes ❒ No ✓

Please give summary of project (max 150 words**):**

The main aim of this research is centred on improving diabetes medicine management amongst Type II diabetic Libyan patients through the use of self-completion questionnaires and semi-structured interviews, and finally randomised controlled trials.

The research is divided into four stages. *The first stage* aims to explore community pharmacists' knowledge, attitudes and practices towards Type II diabetes care. The reason for completing an audit for pharmacists' diabetes knowledge and practices is to gain understanding into the weaknesses and strengths. Stage One is recognised as a descriptive stage; therefore, the study can be seen as using combined methods: a literature review and self-completion questionnaire in order to generate the relevant data that can both inform and provide a clear picture regarding the current situation of the study problem.

The second stage will investigate Type II medicine management barriers of diabetes care amongst patients. During this stage, I sought to understand the barriers amongst community pharmacists and Type II diabetic patients in regard to implementing medicines management. The second stage will utilise a semi-structured interview (*appendix I*) and literature review.

The third stage explores Type II diabetes knowledge, attitudes and practices toward diabetes care through the use of a self-completion questionnaire. The reason for doing this is in order to investigate the various elements of weak diabetes knowledge.

The fourth stage will adopt a randomised controlled trial to improve Type II diabetes disease and medicine management. Once understanding has been gained in regard to Type II diabetes knowledge and practices, as well as the barriers facing community pharmacists and patients from implementing medicine management, the decision will be made as to which study should be used in order to complete such an intervention so as to improve diabetes medicine management

Q1	**Is the proposed project an <u>empirical research</u> project involving people?** • will the project include primary data collection from human subjects, their data or their tissue? • Will it constitute an 'investigation undertaken in order to gain knowledge and understanding'? (this includes work of educational value designed to improve understanding of the research process) If you answer 'Yes' to Q1 ethical approval may be required, move to Q2. If you answer 'No' to Q1 then a research ethics review is <u>not</u> required and you are not required to fill in this checklist. ***Note**: there may be occasions where a project is not defined as research but still raises ethical issues – please submit for review if you think this is the case.*	Yes ❒ No ✓ Yes ❒ No ✓ Yes ❒ No ✓
Q1a	**Is the proposed project an audit involving humans?** A more detailed definition of Research, Audit and Service Evaluation is available on the University Ethics website. If you answered 'Yes' to Q.1a then ethical review is required.	Yes ❒ No ✓
Q2	**Will the research project involve the <u>NHS</u>?** e See Research Ethics and Governance in NHS and Social e page of the website If you answer 'No' to Q2 move on to Q3 If you answer 'Yes' to Q2 ethical approval will be required by NHS Research Ethics Committee (REC)	Yes ❒ No ✓

Q3	**Will the research project involve any of the following in the UK:** Testing a medicinal product Investigating a medical device Taking samples of human biological material (e.g. blood, tissue) Prisoners or others in custodial care (e.g. young offenders) as participants Adults with mental incapacity as participants Other vulnerable groups (e.g. vulnerable children) as participants If you answer 'Yes' to Q3 ethical approval will *usually* be required through Ethical Tissue or NHS Research Ethics Committee (REC) or where the project includes participants which need approval under the Mental Capacity Act approval will be required by the Social Care REC. If you wish to source material from Ethical Tissue at the University, they can be contacted on 01274 235897 or visit www.ethicaltissue.org See information specific to research in Social Care on the versity Ethics website *If you answer 'No' to Q3 move on to Q4*	Yes ❐ No ✓
Q4	**Will the research project involve human participants and/or human data (*but not accessed through the NHS*)?** *If you ticked 'Yes' please give details of:* 1. *Interviews (how many, how long will they last),* ***Number of interviewer 20 and it will take 15-30minutes.*** 2. *who you intend to interview,* ***I intend to interview community pharmacist*** 3. *where interviews will take place and* ***In Tripoli/Libya. In the work place of community pharmacist*** 4. *attach interview guidelines or the questions you intend to ask:* ***See appendix I page: 3-4 in the document of ethical amendment.***	Yes ✓ No ❐

Q5	**Will the research project involve <u>human tissue (but not requiring NHS approval – see Q3)</u>?** If you answer 'Yes' to Q5 University ethical approval is required If you require advice on human biological material please contact Human Tissue Act (HTA) Designated Individual: Dr Sue Boyce [s.g.boyce@bradford.ac.uk] on ext 5897 or visit www.ethicaltissue.org	Yes ❒ No ✓
Q5a	If you answered 'Yes' to Q5, is the human material over 100 years old and archaeological? If 'YES' please refer to the Biological Anthropology Research Centre (BARC) guidelines at http://www.barc.brad.ac.uk/BARC_human_remains_policy.pdf	Yes ❒ No ✓
If you answer 'No' to Q5 and have answered 'No' to Q2, Q3 and Q4 ethical approval is <u>not</u> required.		

PLEASE COMPLETE and SIGN *<u>ONE</u>* of the two boxes below
*(in the case of a student project, we do require a **Supervisor's signature** in whichever box is relevant, before we can have the checklist signed off by the Research Ethics Panel):*

1. I have discussed this project with my student AND/OR
2. I confirm that there are **<u>no ethical issues</u>** requiring further consideration.

(Any subsequent changes to the nature of the project will require that the Panel are informed of all changes)

Signed by (Principal Investigator or Principal Supervisor (in case of student project))**:**

Signature: ……………………………………………… ……. Date: …………………………

PLEASE PRINT NAME …………………………………………………………………………

OR

I confirm that there are **ethical issues** requiring further consideration and will either:

1. refer the proposal to Ethical Tissue, or,
2. fill in and submit a full ethics application to be considered by the appropriate Research Ethics Panel.

Name (Principal Investigator/Principal Supervisor):

Signature: ……………………………………………………….. **Date:** …………………………….

PLEASE PRINT NAME ……………………………………………………………………………..

Annex 1

Ethical Scrutiny by a University Research Ethics Panel is not required if:

- **The project is NOT a research project. There may be occasions where a project is not defined as research but still raises ethical issues – please submit for review if you think this is the case.**

- **The research project will only involve unlinked or aggregated human data which was collected and which was, at the time, subject to relevant research ethics panel approval.**

  However, where this is the case the researcher should at least confirm this in an email to the Research Support Unit's Ethics Administrator so that the Ethics Administrator has a record and can inform the Chair of the appropriate Research Ethics Panel that the researcher plans to go ahead without ethics approval. The email should confirm that the research project does not require ethics approval because it only involves unlinked or aggregated data, which when originally obtained from people was obtained in accordance with the protocol as approved at the time by an appropriate research ethics panel. The email should also briefly explain how the researcher now plans to use the unlinked or aggregated data.

- **The research is Public Domain Data:**

  The Economic and Social Research Council's (ESRC) Research Ethics Framework states that ethics approval may not be required for data sets that exist in the public domain (e.g. datasets that are available from the Office for National Statistics or from the ESRC's Data Archive) so long as the appropriate permissions from individuals have already been obtained (i.e. informed consent) and where it is not possible to identify the individuals from the information provided. It must be remembered that public domain data is still covered by the laws of copyright.

- **The research involves Simple Uncontentious Questionnaires:**

  If a research project's only involvement with human subjects is a simple brief questionnaire with uncontroversial content it may not require ethical approval. It is the Principal Investigator or Principal Supervisor's responsibility to decide whether a project comes under this category and must indicate this at Q.4 on the checklist and attach the questionnaire document for information.

Guidance on supervisor and principal investigator sign off of uncontentious research

Audit and service evaluation are usually uncontentious, and guidance on how to differentiate between research, audit and service evaluation is given at:
University Ethics website.

Even where a project is clearly research, as a supervisor or principal investigator, you can sign off simple, ethically uncontentious projects as not needing further ethical scrutiny. To do this, you should consider the level of risk to participants and researchers, the level of effort required by participants, the level of intrusion into participants' lives and the level of sensitivity of both the general subject matter and the information requested of participants. Basically, the lower these levels, the more likely the research is to be uncontentious and the more confident you should feel about signing off.

The following examples may help.

These studies can almost always be signed off by the supervisor or principal investigator:

- Brief questionnaires asking opinions about matters which are clearly not sensitive (attitudes to a product, beliefs about the usefulness of a course).
- Brief interviews about such topic.
- Observational studies about everyday behaviour in public places which involve no risk to subjects or the researcher.

But the following studies almost always need further scrutiny by a University Ethics Panel:

- Long questionnaires (these require considerable potential inconvenience to subjects).
- Long interviews
- Any questionnaires which ask subjects about intimate behaviours or issue likely to cause distress or would in other ways normally be regarded as contentious or sensitive (e.g. illegal activities, attitudes to abortion, capital punishment, immigration, euthanasia).
- Any interviews which examine these matters.
- Observational studies which involve intimate behaviours, behaviours which are not normally public or which might normally be considered contentious or sensitive (Activities of ethics committees, appointment committees, etc; professional consultations).

Naturally, this list is for illustration only, and should not be considered in any way exhaustive, permissive or prescriptive. For example, there are many categories of research not mentioned here which would definitely require ethics approval (e.g. treatment research). Rather the list demonstrates the issue of proportionality. Thus, even though the method may be the same for activities requiring and not requiring further scrutiny, the *content* in some way distinguishes between the two categories.

At the same time, there is obviously some middle ground. Are ethics committees not public? Is what is discussed so sensitive that the proposal needs further scrutiny? What about asking people about their views on the actions of senior members of staff in their organisation? Probably, it is in these middle ground areas that further advice should be sought from a Panel Chair about whether the project can be signed off by the supervisor or principal investigator alone. Given that, in so doing, the supervisor or PI is attesting to the ethical probity of the study, it is usually best to err on the side of caution where there is uncertainty. Panel chairs are very happy to advise.

(**Dr Martin Brinkworth**, Chair, Biomedical, Natural, Physical and Health Sciences Research Ethics Panel, m.h.brinkworth@bradford.ac.uk, ext. 3584

Dr Clare Beckett, Chair, Humanities, Social and Health Sciences Research Ethics Panel, c.beckett@bradford.ac.uk, ext. 3521)

Please submit this checklist to:

Mr Omar Ali, Ethics Administrator,
RKTS, in hard copy
or by email to ethics@bradford.ac.uk

Appendix 28: FPG recording sheet (Arabic translation)

القراءات الشهرية لقياس مستوى الجلوكوز بالدم

الأيام	التاريخ	قبل الفطور	قبل الغذاء	قبل العشاء	قبل النوم
اليوم الاول					
اليوم الثاني					
اليوم الثالث					

معدل السكري التراكمي

(HbA1c)=........................